

I hereby certify that this correspondence is being deposited with the U.S. Postal Service with sufficient postage as First Class Mail, in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date shown below.

Dated: November 30, 2006

Signature:

(Shawn P. Foley)

PCE-#12
IAP13 Rec'd PCT/PTO 04 DEC 2006

Docket No.: TEVNHC 3.3-103
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of
Woolfe et al

Application No.: 10/516,943

International Appln. No.
PCT/GB03/02669

International Appln. Filing Date:
June 20, 2003

For: PHARMACEUTICAL COMPOSITION

Mail Stop PCT
Commissioner for Patents
Office of PCT Legal Administration
P.O. Box 1450
Alexandria, VA 22313-1450

SECOND RENEWED PETITION UNDER 37 CFR 1.47(a)

Dear Sir:

This is in response to the Decision on Renewed Petition Under 37 CFR 1.47(a) dated October 2, 2006, dismissing the petition without prejudice. It is respectfully requested, in light of the arguments and evidence set forth herein, that this Renewed Petition under 37 CFR 1.47(a) be granted.

Applicant, Norton Healthcare Limited, through its prior counsel, Michael A. Steinberg, filed a Petition Under 37 CFR 1.47(a) on November 17, 2005, to accept the application without the signatures of two joint inventors, namely, Jacqueline Yvonne Allen and Mark Clifford Elliot. In a Decision on Petition mailed February 24, 2006, the petition was dismissed because it did not contain certain statements with respect to providing a complete copy of the application papers to inventor

RECEIVED

8 DEC 2006

Legal Staff
International Division

Allen, and for failure to show the efforts made to contact inventor Elliot.

In the Renewed Petition filed June 26, 2006, Petitioner provided evidence detailing the efforts made to contact the non-signing inventor Allen.

In the PTO's decision, mailed October 2, 2006, it was found that all requirements of 37 CFR 1.47(a) with respect to inventor Allen had been satisfied. With respect to inventor Elliot, however, the Decision states:

Since attempts to locate inventor Elliot were insufficient, it can not be concluded that a "diligent effort" was made to locate the non-signing inventor. The action taken by petitioner is not sufficient to prove that a "diligent effort" was made to contact the nonsigning inventor. Under these circumstances, it cannot be concluded that Mr. Elliot is unavailable to sign the application.

The Attorney Advisor recommended in her Decision that the petitioner should pursue further efforts to show diligent attempts to locate Mr. Elliot. It is believed the present renewed petition and attachments satisfy this requirement.

The attached Affidavit of Samantha Claire Radley, Patent Administrator for Norton Healthcare Limited, documents her own efforts in a diligent attempt to locate Mr. Elliot. Specifically, it states that she conducted various internet searches to obtain the telephone number or any information relating to inventor Elliot. She also attempted to obtain information from a former colleague as well as Norton's Human Resources Department. Further, the United Kingdom Post Office was contacted regarding a "redirection advice" for inventor Elliot. All attempts to locate Mr. Elliot failed.

In view of the foregoing, Applicants respectfully submit that the requirements set forth in the PTO's decision have now been satisfied as they relate to inventor Elliot. Since all other requirements had already been satisfied, it is respectfully requested that the present renewed petition be granted.

It is believed that no petition fee is due. However, if there are any fees due and owing, the PTO is authorized to charge Deposit Account No. 12-1095 therefor.

Dated: November 30, 2006

Respectfully submitted,

By Shawn P. Foley
SHAWN P. FOLEY
Registration No.: 33,071
Under 37 CFR 1.34(a)
LERNER, DAVID, LITTENBERG,
KRUMHOLZ & MENTLIK, LLP
600 South Avenue West
Westfield, New Jersey 07090
(908) 654-5000
Attorney for Applicant

Filed on behalf of Norton Healthcare Limited
Deponent: S. C. Radley
First Affidavit of the Deponent
Date of Swearing: 27 November 2006
Exhibits: SR1-6

IN THE MATTER of United States Patent Application Number 10/516,943

AFFIDAVIT OF SAMANTHA CLAIRE RADLEY

I, SAMANTHA CLAIRE RADLEY, of 79a Gellatly Road, London SE14 5TU
Patent Administrator, MAKE OATH and say as follows:

1. I am a Patent Administrator for Norton Healthcare Limited (Norton) and I make this affidavit in support of Norton's United States patent application number 10/516,943 entitled "Pharmaceutical Composition". In so far as the content of this affidavit is within my personal knowledge it is true, and so far as it is not within my personal knowledge it is true to the best of my knowledge information and belief.
2. On 24 October 2006 I interrogated an internet based website called 192.com that holds current United Kingdom electoral roll details and residential telephone numbers for residents in the United Kingdom for "Mark C Elliot". The web site returned no results for Mark Clifford Elliot. Instead the only result returned was for Mark Collier Elliot. I present a printout of that search as exhibit "SR1".
4. On 24 October 2006 I interrogated an internet based website called The Phone Book which holds residential telephone numbers for residents in the United Kingdom for "M C Elliot in London". The web site returned no results. I present a printout of that search as exhibit "SR2".
5. On 24 October 2006 I interrogated an internet based website called Google.co.uk for "Mark Clifford Elliot". The web site returned no results for Mark Clifford Elliot. I present a printout of that search as exhibit "SR3".
6. On 24 October 2006, I read the Affidavit of Simone Frankel sworn in this case 10 April 2006. I noted that the last known address for Mark Clifford Elliot was 40 Farleigh Road, Stoke Newington, London N16 7TH.
7. On, or about 24 October 2006, I asked a former colleague of Mark Clifford Elliot named Dr. John Man whether he knew of Mark Clifford Elliot's present whereabouts. Dr. Man did not know the whereabouts of Mark Clifford Elliot as he had had no contact with him since he left the employment of Norton.

8. On 22 November 2006, I contacted Jaz Ghick of Norton's Human Resources Department to ensure that the last known address Norton had for Mark Clifford Elliot had not been updated or changed from that present in Simone Frankel's affidavit. The address that the Human Resources Department had was 40 Farleigh Road, Stoke Newington, London N16 7TH. However a request for an employment reference had been made by SRG limited of Buckland House, Waterside Drive, Langley Business Park, Slough SL3 6EZ.

9. On 22 November 2006, I spoke to Glen Harris of SRG Limited who informed me that they had had no contact with Mark Clifford Elliot since February 2006 and that he was unable to divulge the contact details on their records under the United Kingdom Data protection Acts but he would attempt to pass a message to Mark Clifford Elliot. I asked him to ask Mark Clifford Elliot to contact me urgently and gave him my direct dial telephone number. A telephone note of this conversation is attached as exhibit "SR4" to this affidavit.

10. Later, on 22 November 2006, Glen Harris contacted me to inform me that he had attempted to ring two different contact telephone numbers for Mark Clifford Elliot but in both cases the lines were dead. He told me he had also attempted to send an email but the email was reported as failed to be delivered. He told me that he could not contact Mark Clifford Elliot. A telephone note of this conversation is attached as exhibit "SR5" to this affidavit.

11. On 22 November 2006, I contacted the United Kingdom Post Office customer services department. I enquired whether they had a redirection advice for Mark Clifford Elliot for his last known address: 40 Farleigh Road, Stoke Newington, London N16 7TH. I was informed that they did not have such a redirection advice. A telephone note of this conversation is attached as exhibit "SR6" to this affidavit.

Sworn at.....
CLIFFORD CHANCE
10 UPPER BANK STREET
LONDON E14 5JJ
this 27th day of
NOVEMBER 2006

Signature of Deponent making the Affidavit

Before me,

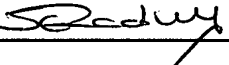
..... GARY SHINDA BORGAN
..... PRACTISING SOLICITOR
.....
.....
.....

Signature of Authorised Witness

CLIFFORD CHANCE
Limited Liability Partnership
10 Upper Bank Street
London E14 5JJ

IN THE MATTER of United States Patent Application Number 10/516,943

EXHIBIT SR1 TO THE
AFFIDAVIT OF SAMANTHA CLAIRE RADLEY



SAMANTHA CLAIRE RADLEY



PRACTISING SOLICITOR

[Sign In](#) [Get Credits](#) [Help & Supp](#)**192.com™**Best online service at the **900** awards**192.com wins best online ser**[Search All](#)[Business](#)[People](#)[Family Records](#)[Local](#)[Maps & Travel](#)[Tell a friend](#) [Bookmark this page](#)

Search the most powerful people and business finder in the UK. With 500 million people and business records, there is no better place to search.

I am looking for:

Name of person or business type (eg. John Smith or Chemists)

Location:

Any part of address or postcode (eg. London, Fulham or SW6)

[Search Now](#)**Find People**

- Electoral Roll 2006
- Electoral Roll 2002 - 2005
- Directory Enquiries
- UK-Info
- Residential Listings
- 192 Dating
- Births, Marriages, Deaths
- Census Records
- House Prices
- Track a Mobile
- 118 119

Find Businesses

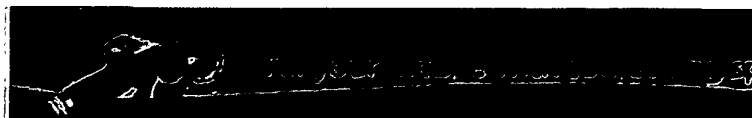
- Business Search
- Local Search
- Thomson Directories
- Dun & Bradstreet
- Company Reports
- Director Reports
- Directory Enquiries
- Directions
- 118 119

Find Places

- Maps
- Directions
- Aerial Photographs
- Property Prices

Business S

- Fraud Prev
- Identity Ver
- Age Verific
- Debtor Tra
- Online Dire
- **XML**



Maps & Travel

New Search

Full Details:

XX

1 of 1 result

new search

No results found

Require both name and location

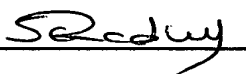
No results found

No results found

Need help refining your search? Call 118 119 for

IN THE MATTER of United States Patent Application Number 10/516,943

EXHIBIT SR2 TO THE
AFFIDAVIT OF SAMANTHA CLAIRE RADLEY



SAMANTHA CLAIRE RADLEY



PRACTISING SOLICITOR

The Phone Book

[Home](#)[Find a number](#)[Advertise with us](#)[Knowledge centre](#)

You are here: [Find a number](#) > [Residential numbers](#)

Residential numbers

[Residential numbers](#)[Help](#)

I am looking for a person by name preferences

surname

initials

town or postcode

street

elliott

m c

London

**find a
number**

[Residential numbers](#)[Business numbers](#)[UK dial codes](#)[International dial
codes](#)

Searched for elliot, m c in and around london

Please select one of the following:

1. London
2. London Airport { West Drayton - Middlesex}
3. London Apprentice { St Austell - Cornwall}
4. London Bridge { London SE1}
5. London Colney { St Albans - Hertfordshire}
6. London Fields { London E8}
7. London Minstead { Lyndhurst - Hampshire}

[Directory Entitlement](#) • [Advertiser Information](#) • [Contact BT](#) • [About BT](#) • [Privacy policy](#) •

[BT home](#) • [Fersiwn Cymraeg](#)

The Phone Book

[Home](#)[Find a number](#)[Advertise with us](#)[Knowledge centre](#)

You are here: [Find a number](#) > [Residential numbers](#)

Residential numbers

[Residential numbers](#)[Help](#)

I am looking for a person by name preferences

surname

initials

town or postcode

street

find a number

[Residential numbers](#)[Business numbers](#)[UK dial codes](#)[International dial
codes](#)

Searched for elliot, m c in and around London

The person could not be found

The number you are searching for may be ex-directory. Alternatively, please see suggestions below.

Suggestions

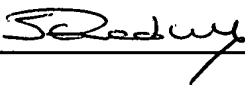
Try searching again using the following tips:

1. Check your spelling
2. Try an alternative surname
3. Reduce the surname to first 4 letters followed by an * e.g. Brit*
4. Try changing the search preferences

[Directory Entitlement](#) • [Advertiser Information](#) • [Contact BT](#) • [About BT](#) • [Privacy policy](#) •

IN THE MATTER of United States Patent Application Number 10/516,943

EXHIBIT SR3 TO THE
AFFIDAVIT OF SAMANTHA CLAIRE RADLEY



SAMANTHA CLAIRE RADLEY



PRACTISING SOLICITOR

[Sign in](#)

[Go to Google Home](#)

[Web](#) [Images](#) [Groups](#) [News](#) [Froogle](#) [more »](#)

"mark clifford elliot"

Search

[Advanced Search](#)
[Preferences](#)

Search: ☒ the web ☐ pages from the UK

Web

Tip: Try removing quotes from your search to get more results.

Your search - **"mark clifford elliot"** - did not match any documents.

Suggestions:

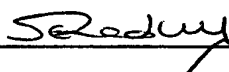
- Make sure all words are spelled correctly.
- Try different keywords.
- Try more general keywords.

[Google Home](#) - [Advertising Programmes](#) - [Business Solutions](#) - [About Google](#)

©2006 Google

IN THE MATTER of United States Patent Application Number 10/516,943

EXHIBIT SR4 TO THE
AFFIDAVIT OF SAMANTHA CLAIRE RADLEY



SAMANTHA CLAIRE RADLEY



PRACTISING SOLICITOR

Note of Telephone Conversation between Samantha Radley and Glen Harris On 22 November 2006 at 14.30pm.

I asked Glen Harris if they had Mark Clifford Elliot on their records as, according to Norton Healthcare files, they had approached Norton for a reference for Mark Clifford Elliot in January 2005.

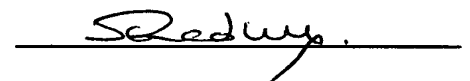
He confirmed that Mark Clifford Elliot was on their records but he was unable to divulge any contact details that they had because of the United Kingdom Data Protection Act.

He agreed to try and contact Mark Clifford Elliot on my behalf and pass on a message to him to contact me urgently on my direct dial telephone extension at Norton Healthcare Ltd.

S Radley 22/11/06.

IN THE MATTER of United States Patent Application Number 10/516,943

EXHIBIT SR5 TO THE
AFFIDAVIT OF SAMANTHA CLAIRE RADLEY


SAMANTHA CLAIRE RADLEY


PRACTISING SOLICITOR

Note of Telephone Conversation between Glen Harris and Samantha Radley On 22 November 2006 at 15.30pm.

Glen Harris told me that attempts to call Mark Clifford Elliot on the two telephone numbers that he had on his records were unsuccessful and an email that he had sent had been returned undeliverable.

S Radley 22/11/06 .

IN THE MATTER of United States Patent Application Number 10/516,943

EXHIBIT SR6 TO THE
AFFIDAVIT OF SAMANTHA CLAIRE RADLEY



SAMANTHA CLAIRE RADLEY



PRACTISING SOLICITOR

Note of Telephone Conversation between Post Office Customer Services and
Samantha Radley On 22 November 2006 at 16.00pm.

The Post Office Customer Services department confirmed that there was no
redirection address for Mark Clifford Elliot at 40 Farleigh Road, Stoke Newington,
London N16 7TH.

S Radley. 22/11/06.

Ex. A

Filed on behalf of Norton Healthcare Limited
Deponent: D. W. Cottam
First Affidavit of the Deponent
Date of Swearing: 10 April 2006
Exhibits: DC1-6

IN THE MATTER of United States Patent Application Number 10/516,943

AFFIDAVIT OF DAVID WILLIAM COTTAM

I, DAVID WILLIAM COTTAM, of 13 Newington Green Mansions, London, N16 9BT, barrister at law, MAKE OATH and say as follows:

1. I am Intellectual Property Counsel for Norton Healthcare Limited (Norton) and I make this affidavit in support of Norton's United States patent application number 10/516,943 entitled "Pharmaceutical Composition". In so far as the content of this affidavit is within my personal knowledge it is true, and so far as it is not within my personal knowledge it is true to the best of my knowledge information and belief.
2. On 22 June 2005 Annette Cunningham asked me to contact Jacqueline Allen regarding the above-mentioned patent application. Annette gave me Jacqueline Allen's cell phone number. I telephoned Jacqueline Allen on her cell phone and left a voice mail stating that I was wanted to discuss the legal situation regarding the signing of the USPTO documents that she had been sent by Simone Frankel in December 2004. I never received a reply to this voice mail message (appended as Exhibit DC1).
3. On 24 June 2005 I telephoned Jacqueline Allen on her cell phone and left a voice mail stating that I wanted to advise her on the legal situation regarding the signing of the USPTO documents that she had been sent by Simone Frankel. I never received a reply to this voice mail message (appended as Exhibit DC1).
4. On 27 June 2005 I telephoned Jacqueline Allen on her cell phone and left a voice mail stating that I was happy to discuss the legal situation regarding the signing of the documents that she had been sent by Simone Frankel. I never received a reply to this voice mail message (appended as Exhibit DC1).
5. On 4 August 2005 I sent an email to Jacqueline Allen's work email address (appended as Annex DC2, page 1) but received a delivery failure report (appended as Exhibit DC2, page 2).
6. On 8 August 2005 I telephoned Jacqueline Allen on her cell phone and she answered the telephone. I told her that I needed her to sign the documents that Simone Frankel had sent to her in December 2004. I explained that her rights in the

application passed by virtue of her employment contract to Norton Healthcare Limited and that she was required by her contract of employment to sign the USPTO documents.

7. Jacqueline Allen told me that she wanted independent legal advice about her rights. I told her that I could arrange for an external patent attorney to advise her free of charge. This was not acceptable to her and she told me that she wanted to choose her own attorney. I replied that I would send through the USPTO papers for her along with a list of attorneys close to where she lived. I asked her about Mark Elliot's current whereabouts, she told me that he had moved from the address listed on his employment contract and that she did not know his current address (appended as Exhibit DC3).

8. I asked Mark Elliot's former colleagues Sophia Chew, Modupe Oladapo, John Woolfe and Martin Oliver if they knew Mark Elliot's current address. Each of them told me that they did not. John Woolfe told me that the last he had heard was that Mark Elliot was living in a tent somewhere on the South coast of England and was moving around the countryside as he wished. In these circumstances it would be impossible to contact Mark Elliot.

9. On 9 August 2005 I sent Jacqueline Allen a bundle of documents (appended as Exhibit DC4)

10. On 3 September 2005 the bundle of documents was returned because Jacqueline Allen had refused to accept delivery of the package (a photocopy of the returned package is appended as Exhibit DC5).

11. On 5 September I telephoned Jacqueline Allen's cell phone and could get no reply (Exhibit DC6).

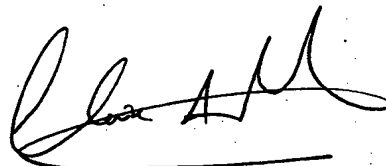
Sworn at, *Clifford Chance LLP*
10 Upper Bank Street
London
E14 5JJ
this *10th* day of
April 2006



Signature of Deponent making the Affidavit

Before me,

Clifford Chance LLP
10 Upper Bank Street
London E14 5JJ
(Solicitor)



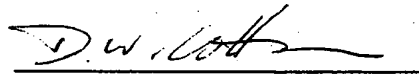
Signature of Authorised Witness - *So C. A. R.*

CLIFFORD CHANCE
Limited Liability Partnership
10 Upper Bank Street
London E14 5JJ

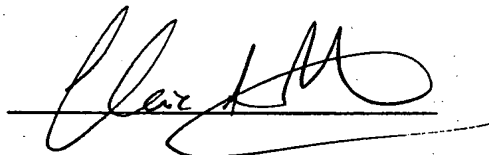
Filed on behalf of Norton Healthcare Limited
Deponent: D. W. Cottam
First Affidavit of the Deponent
Date of Swearing: 10 April 2006

IN THE MATTER of United States Patent Application Number 10/516,943

EXHIBIT "DC1" TO THE AFFIDAVIT OF DAVID WILLIAM COTTAM



DAVID WILLIAM COTTAM



PRACTISING SOLICITOR

22/6/05 Note of telephone call to Jacqueline Allen

I phoned Jackie's mobile and asked her to call me back so that I could explain UK and US patent law to her.

D. W. Cotton 22/6/05

24/6/05 Note of phone call to Jacqueline Allen

I phoned Jackie again and asked her to call me back so that I could explain the situation re to USPTO documents to her.

D. W. Cotton 24/6/05

27/6/05 Note of phone call to Jacqueline Allen

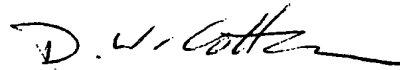
called Jackie again, asked her to call me.

D. W. Cotton 24/6/05

Filed on behalf of Norton Healthcare Limited
Deponent: D. W. Cottam
First Affidavit of the Deponent
Date of Swearing: 10 April 2006

IN THE MATTER of United States Patent Application Number 10/516,943

EXHIBIT "DC2" TO THE AFFIDAVIT OF DAVID WILLIAM COTTAM



DAVID WILLIAM COTTAM



PRACTISING SOLICITOR

David
Cottam/London/UK/IVAX
04/08/2005 10:51

To JAllen@pharmalytic.com
cc
bcc
Subject Patent application signature

Dear Jackie,

I am now in charge of getting the patent application on which you are an inventor (Pharmaceutical Composition) granted as a patent in the US. As you are aware, following conversations with Annette Cunningham, we seem to have reached an impasse with the US case. The usual way forward is for the inventors to sign an assignment and a declaration. This is usually routine but occasionally an employee will not be able to be found or has died etc. In order to deal with this situation US law has provisions that allow the documents to be deemed to have been signed.

Unfortunately this procedure is tedious and time consuming. I can use this procedure but would prefer to have your cooperation with this matter. I rang you about a month ago on what I believed was your mobile number and left a message, I seemed to have missed your reply. I do not know what the problem is with getting your signature but would be glad to, at least, explain the situation to you.

Patent law is complex, especially when it is in a foreign jurisdiction, and I appreciate that you may be apprehensive. In England, an employee automatically transfers their rights in an invention or patent to their employer by virtue of their employment, no express clauses are needed in the employment contract. I can provide a copy of the Act of Parliament that will confirm this if you like. In the US they have a different system and do not have such a provision but are lead by the law in the country in which the invention was made. In order to confirm the situation, the US Patent and Trade mark Office usually require a documents that says, in effect, I am an inventor (the declaration) and another that says I have transferred my rights to the company that employed me when I made the invention (the assignment). As you will appreciate in English law you are an inventor because you helped to devise the inventive concept of the patent application and you have already assigned you rights to IVAX by operation of English law. All we require from you and Mark is a confirmation that you are inventors and that you were employed by IVAX when you made the invention i.e. your signature on the assignment and declaration.

Please ring me to discuss this with me if you wish, or send me an email. I have spoken to an external patent agent based in Sevenoaks and he has agreed to discuss this with you. If you are interested I will give you his contact details. I shall ensure that this advice is free of charge to you and can be given either over the phone, in Sevenoaks, or wherever it is convenient for you and Mark. If you have to travel I will ensure that your expenses are paid by IVAX.

On a purely selfish level, if you sign these documents I will be saved a lot of work. I will do whatever I can to help you come to an informed decision. If you and Mark still do not wish to sign after free legal advice please let me know as soon as possible so that I can get working on this. Thanks.

Best regards.

David

Delivery Failure Report

Your document: Patent application signature
was not delivered to: JAllen@pharmalytic.com
because: User JAllen (JAllen@pharmalytic.com) not listed in Domino Directory

What should you do?

- You can resend the undeliverable document to the recipients listed above by choosing the Resend button or the Resend command on the Actions menu.
- Once you have resent the document you may delete this Delivery Failure Report.
- If resending the document is not successful you will receive a new failure report.
- Unless you receive other Delivery Failure Reports, the document was successfully delivered to all other recipients.

Routing path

IVAXCOMM-LON1/HUBSRV/IVAX, IVAXMAIL-LON1/MAILSRV/IVAX

To: JAllen@pharmalytic.com

cc:

Date: 10:51:10 CET Today

Subject: Patent application signature

Dear Jackie,

I am now in charge of getting the patent application on which you are an inventor (Pharmaceutical Composition) granted as a patent in the US. As you are aware, following conversations with Annette Cunningham, we seem to have reached an impasse with the US case. The usual way forward is for the inventors to sign an assignment and a declaration. This is usually routine but occasionally an employee will not be able to be found or has died etc. In order to deal with this situation US law has provisions that allow the documents to be deemed to have been signed.

Unfortunately this procedure is tedious and time consuming. I can use this procedure but would prefer to have your cooperation with this matter. I rang you about a month ago on what I believed was your mobile number and left a message, I seemed to have missed your reply. I do not know what the problem is with getting your signature but would be glad to, at least, explain the situation to you.

Patent law is complex, especially when it is in a foreign jurisdiction, and I appreciate that you may be apprehensive. In England, an employee automatically transfers their rights in an invention or patent to their employer by virtue of their employment, no express clauses are needed in the employment contract. I can provide a copy of the Act of Parliament that will confirm this if you like. In the US they have a different system and do not have such a provision but are lead by the law in the country in which the invention was made. In order to confirm the situation, the US Patent and Trade mark Office usually require a documents that says, in effect, I am an inventor (the declaration) and another that says I have transferred my rights to the company that employed me when I made the invention (the assignment). As you will appreciate in English law you are an inventor because you helped to devise the inventive concept of the patent application and you have already assigned you rights to IVAX by operation of English law. All we require from you and Mark is a confirmation that you are inventors and that you were employed by IVAX when you made the invention i.e. your signature on the assignment and declaration.

8/8/05 Note of phone call to Jackie Allen

Spoke to Jackie

Told her I needed her to sign the USPTO documents ASAP.

Explained automatic assignment, by virtue of a contract of employment, of her rights in NHC 10305 to Naitan Healthcare Ltd.

Explained what the documents were

Told her I had arranged for Nick Kirkham of Graham Watt & Co to advise her

she wanted to choose her own attorney. I told her I'd send through a list of attorneys in London.

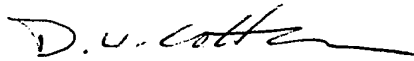
Asked her if she knew Mark's address - she didn't know where he lives now.

D. Wroth 8/8/05

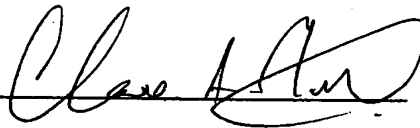
Filed on behalf of Norton Healthcare Limited
Deponent: D. W. Cottam
First Affidavit of the Deponent
Date of Swearing: 10 April 2006

IN THE MATTER of United States Patent Application Number 10/516,943

EXHIBIT "DC4" TO THE AFFIDAVIT OF DAVID WILLIAM COTTAM



DAVID WILLIAM COTTAM



PRACTISING SOLICITOR



Subsidiary of **IVAX** Corporation

Ms Jacqueline Allen,
19 Peartree Avenue,
Earlsfield,
London
SW17 0JG

Norton Quays
Albert Basin, Royal Docks
London E16 2QJ
Telephone 08705 02 03 04
Fax 08705 32 33 34

9 August 2005

Dear Jackie,

Re: our ref: NHC103US
Entitled: Pharmaceutical Composition (PCT/GB2003/002669 filed 20 June 2003)

Further to our telephone conversation on 4 August 2005, please find enclosed a list of patent attorneys in the London area who should be able to advise you on the US law and employment issues which are concerning you. In particular, I believe that these issues are the nature and wording of the assignment agreement between you and Norton Healthcare Limited, the power of attorney and the declaration for utility or design patent application.

I enclose copies of these documents along with an information disclosure statement (the patent attorney who advises you will explain this document). I also enclose a copy of the patent application and your employment contract with Norton Healthcare Limited which will be of use to the patent attorney whom you select to advise you. Please draw the attorney's attention to the section entitled "INVENTIONS" on page 5, in particular the last sentence:

"You shall at the Company's request and expense take all the necessary steps to ensure that all rights shall, subject to the provisions of the Patents Act 1977, become the property of the Company or its nominee."(emphasis added)

The right to the grant of a United States patent is a right that the Company has requested you take steps to ensure it receives.

The due date for the receipt of the signed documents by the US Patent and Trademark Office was the **17 July 2005**. Extensions to this due date are available but the extensions are increasingly expensive for each additional month.

If after you have received your advice you still decide to refuse to sign, please let me know so that I can set the wheels in motion to start the legal procedure to have the application progress on the basis that you are an inventor who has refused to acknowledge that they are an inventor, refuses to authorise a representative and refuses to sign a standard assignment document. Please send back the signed documents or let me know your final decision by **24 August 2005** so that I can keep any unnecessary expenses to a minimum.

I expect that the time you will spend with the patent attorney will be quite short and that your travel expenses will be small. I have secured approval for expenses to a ceiling of £500 for this legal advice and co-incidental expenses such as travel and food. I leave it to you whether you want the attorney to invoice Norton Healthcare Limited directly or whether you want them to invoice you and then you forward the invoice on to me for payment.

Norton Healthcare Limited reserves its right to enforce the employment contract to the full extent of the law and recover any unnecessary costs and expenses that are incurred by your actions or inaction.

Yours sincerely

A handwritten signature in dark ink, appearing to read "D. W. Cottam". The signature is fluid and cursive, with a large initial "D" and a stylized "W".

Dr. David W. Cottam
Intellectual Property Counsel

Google

Local BETA

[Web](#) [Images](#) [Groups](#) [News](#) [Froogle](#) [Local](#) [more »](#)

category: Patent Agents

London, UK

Search

What

Where

☐ Remember this location**Local**Search within: [1 mile](#) - [5 miles](#) - [15 miles](#) - [45 miles](#)Calling All Inventors

Don't let this Opportunity pass by!
Visit now for a Free Inventors Kit
www.InventorsHelpline.Info

Intellectual property

Business link gives guidance on
protecting intellectual property
www.businesslink.gov.uk

European Patent Attorneys

Patents, designs, trade marks
and copyright.
www.appleyardlees.com

Sp

A. R.G.C Jenkins & Co
020 7931 7141

26 Caxton St
London, SW1H 0RJ
0.5 mi W - [Directions](#)

References: piperpat.co.nz - [98 more »](#)

B. Dr Walther Wolff & Co
020 7828 1441

19 Catherine Place
London, SW1E 6DX
0.7 mi W - [Directions](#)

References: patent.gov.uk - [4 more »](#)

C. Page Hargrave
020 7240 6933

Manfield House
1 Southampton St
London, WC2R 0LR
0.8 mi N - [Directions](#)

References: pagehargrave.co.uk

D. Forrester, Ketley & Co
020 8889 6622

105 Piccadilly
London, W1J 7NJ
0.9 mi W - [Directions](#)

References: forresters.co.uk

E. Electronic Intellectual Property
020 7721 7152

Suite 308 The Foundry, 156
London, SE1 8EN
0.9 mi E - [Directions](#)

F. WP Thompson & Co & John Orchard
020 7240 2220

55 Drury Ln
Camden, WC2E 7AA
1.0 mi N - [Directions](#)

References: itma.org.uk - [3 more »](#)

G. Haseltine Lake
020 7420 0500

Imperial House
15-19 Kingsway
London, WC2B 6UD
1.0 mi N - [Directions](#)

H. Mewburn Ellis LLP
020 7240 4405

York House
23 Kingsway
London, WC2B 6HP
1.0 mi N - [Directions](#)

References: mewburn.com - [4 more »](#)[View Larger Map](#)

I. Hoffmann . Eitle
(U.K)
020 7404 0116
Sardinia House
52 Lincolns Inn Fields
London, WC2A 3LZ
1.1 mi N - Directions

J. Fitzpatricks
020 7522 9001
39 Stukeley St
London, WC2B 5LT
1.1 mi N - Directions

Google ►

Result Page: 1 2 3 4 5 [Next](#)

category: Patent Agents

London, UK

Search

What

Where

☐ Remember this location

[Local Search Home](#) - [Google Home](#) - [Terms of Use](#) - [Local Search Help](#)

Business listings provided by [Yell.com](#)™

Map data ©Crown copyright. License number 100026920
©2005 Google

Google

Local BETA

[Web](#) [Images](#) [Groups](#) [News](#) [Froogle](#) [Local](#) [more »](#)

category: Patent Agents

London, UK

Search

What

Where

☐ Remember this location

Local

Search within: [1 mile](#) - [5 miles](#) - [15 miles](#) - [45 miles](#)

European Patent Attorneys
International Patent Filing,
Prosecution & Litigation
www.wilsongunn.com

European Patent Attorneys
Experienced service covers, patents
trade marks, copyright and designs.
www.franksco.com

Free Patent Information
Need a Patent? Free, complete
information. Easy to Understand.
www.IPEsqire.org

Sp

A. Lloyd Wise
Tregear & Co
020 7571 6200

Commonwealth House
1-19 New Oxford St
London, WC1A 1LW
1.2 mi N - Directions

References: [fpp.co.uk](#) - 26 more »

B. Elkington &
Fife
020 7405 3505

Beacon House
113 Kingsway
London, WC2B 6PN
1.2 mi N - Directions

C. Chartered
Institute of
Patent
Agents
020 7405 9450

95 Chancery Ln
City of London, WC2A 1DT
1.2 mi NE - Directions

References: [cipa.org.uk](#) - 80 more »

D. Bromhead
Johnson
020 7405 0356

Kingsbourne House
229-231 High Holborn
London, WC1V 7DP
1.2 mi N - Directions

References: [piperpat.co.nz](#) - 34 more »

E. Frank B Dehn
020 7206 0600

179 Queen Victoria St
London, EC4V 4EL
1.3 mi NE - Directions

References: [frankbdehn.com](#) - 210 more »

F. Beck, Greener
& Co
020 7405 0921

7 Stone Building, Lincoln's Inn
London, WC2A 3SZ
1.3 mi NE - Directions

G. Phillips &
Leigh
020 7822 8888

5 Pemberton Row
London, EC4A 3BA
1.3 mi NE - Directions

References: [pandl.com](#) - 30 more »

H. F.J Cleveland
020 7405 5875

40 Chancery Ln
City of London, WC2A 1JQ
1.3 mi NE - Directions

References: [fjcleveland.com](#) - 1 more »

I. Carpmaels &

43 Bloomsbury Square



View Larger Map

Ransford
020 7242 8692

London, WC1A 2RA
1.3 mi N - Directions

References: [carpmaels.com](#) - **115 more »**

J. **W H Beck**
Greener & Co
020 7242 2535

7 Stone Buildings
City of London, WC2A 3SZ
1.3 mi NE - Directions

References: [beckgreener.com](#) - **43 more »**

◀ **Google** ▶

Result Page: **Previous** [1](#) [2](#) [3](#) [4](#) [5](#) **Next**

category: Patent Agents

London, UK

Search

What

Where

☐ Remember this location

[Local Search Home](#) - [Google Home](#) - [Terms of Use](#) - [Local Search Help](#)

Business listings provided by [Yell.com](#)™

Map data ©Crown copyright. License number 100026920
©2005 Google

Google

Local BETA

[Web](#) [Images](#) [Groups](#) [News](#) [Froogle](#) [Local](#) [more »](#)

category: Patent Agents

London, UK

Search

What

Where

☐ Remember this location

Local

Search within: [1 mile](#) - [5 miles](#) - [15 miles](#) - [45 miles](#)

Patent Law Information

Patent solutions and information
from a respectable legal authority.
www.legal-database.com

Got an idea but no Design

Photorealistic Images will help
to Convince & Encourage Investors!
EngineeringDreams.com

Patent Search - Now Free

The smart way to find patents.
Online, without registration.
www.search4ip.com

Sp

- A. A.A.Thornton & Co
020 7405 4044
References: locallife.co.uk
- 306 High Holborn
Camden, WC1V 7LE
1.3 mi N - Directions

- B. Langner Parry
020 7242 5566
References: ladas.com - 25 more »
- High Holborn House
52-54 High Holborn
London, WC1V 6RR
1.3 mi N - Directions

- C. Abel & Imray
020 7242 9984
References: patentable.co.uk - 67 more »
- 20 Red Lion St
London, WC1R 4PQ
1.4 mi N - Directions

- D. Kilburn & Strode
020 7539 4200
References: kstrode.co.uk - 117 more »
- 20 Red Lion St
London, WC1R 4PJ
1.4 mi N - Directions

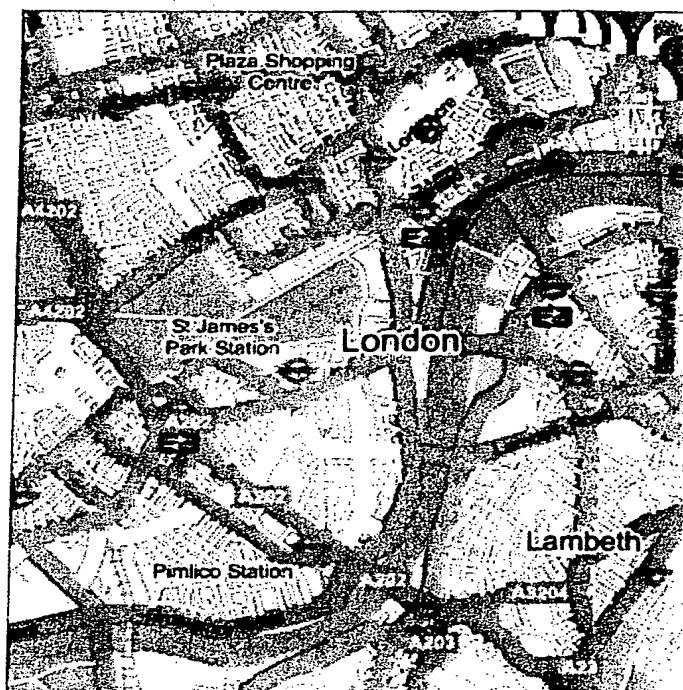
- E. David Keltie Associates
020 7329 8888
References: keltie.com - 141 more »
- Fleet Place House
2 Fleet Place
London, EC4M 7ET
1.4 mi NE - Directions

- F. Stevens, Hewlett & Perkins
020 7404 1955
- Halton House
20-23 Holborn
London, EC1N 2JD
1.4 mi NE - Directions

- G. Beresford & Co
020 7831 2290
References: ffii.org - 24 more »
- 16 High Holborn
London, WC1V 6BX
1.4 mi NE - Directions

- H. Mathys & Squire
020 7269 1500
References: mathys-squire.com - 58 more »
- 120 Holborn
London, EC1N 2TD
1.4 mi NE - Directions

- I. D. Young & Co
020 7269 8550
- 120 Holborn
London, EC1N 2DY
1.4 mi NE - Directions



View Larger Map

References: [dyoung.com](#) - **165 more »**

J. [Elkington & Fife](#) Holborn Circus
[Llp](#) London, EC1N 2HB
020 7936 8800 1.4 mi NE - Directions

◀ Google ▶

Result Page: [Previous](#) [1](#) [2](#) [3](#) [4](#) [5](#) [Next](#)

category: Patent Agents

London, UK

Search

What

Where

☐ Remember this location

[Local Search Home](#) - [Google Home](#) - [Terms of Use](#) - [Local Search Help](#)

Business listings provided by [Yell.com](#)™

Map data ©Crown copyright. License number 100026920
©2005 Google

Google

Local BETA

[Web](#) [Images](#) [Groups](#) [News](#) [Froogle](#) [Local](#) [more »](#)

category: Patent Agents

London, UK

Search

What

Where

☐ Remember this location

Local

Search within: [1 mile](#) - [5 miles](#) - [15 miles](#) - [45 miles](#)

Patent Attorney

File your patent application in
18 countries in America and Europe
www.patentarea.com

Patent Agents

Companies & classified listings for
Patent Agents
www.118.com

Patent agents

Search for Patent agents
online - fast results.
www.Tunu.com

Sp

A. **Fry Heath &
Spence LLP**
020 7400 6260

114 Southampton Row
London, WC1B 5AA
1.4 mi N - [Directions](#)

B. **Hughes Clark
& Co**
020 7400 6262

114-118 Southampton Row
London, WC1B 5AA
1.4 mi N - [Directions](#)

C. **J.A Kemp &
Co**
020 7405 3292

14 South Square
Grays Inn, London, WC1R 5EU
1.4 mi NE - [Directions](#)

D. **Williams
Powell**
020 7936 3300

26-30 Holborn Viaduct
London, EC1A 2BP
1.5 mi NE - [Directions](#)

References: williamspowell.com

E. **Boulton Wade
Tennant**
020 7430 7500

Verulam Gardens
70 Gray's Inn Rd
London, WC1X 8BT
1.5 mi N - [Directions](#)

References: boulton.com

F. **Prentice &
Matthews**
020 7403 8565

Calverts Buildings
52b Borough High St
London, SE1 1XN
1.5 mi E - [Directions](#)

G. **Miller Sturt
Kenyon Ltd**
020 7242 5974

9 John St
London, WC1N 2ES
1.5 mi N - [Directions](#)

References: piperpat.co.nz - [10 more »](#)

H. **Reddie &
Grose**
020 7242 0901

16 Theobald's Road
City of London, WC1X 8PL
1.6 mi N - [Directions](#)

References: reddie.co.uk - [1 more »](#)

I. **Urquhart-
Dykes & Lord**

30 Welbeck Street
Camden, W1H 1AD



[View Larger Map](#)

020 7487 1550 1.6 mi NW - Directions

References: [udl.co.uk](#) - **63 more »**

**J. Page White &
Farrer**

**54 Doughty St
London, WC1N 2LS**

020 7831 7929

1.7 mi N - Directions

References: [pagewhite.co.uk](#) - **47 more »**



Result Page: **Previous** [1](#) [2](#) [3](#) [4](#) [5](#) **Next**

category: Patent Agents

London, UK

Search

What

Where

☐ Remember this location

[Local Search Home](#) - [Google Home](#) - [Terms of Use](#) - [Local Search Help](#)

Business listings provided by [Yell.com](#)TM

Map data ©Crown copyright. License number 100026920
©2005 Google

Google

Local BETA

[Web](#) [Images](#) [Groups](#) [News](#) [Froogle](#) [Local](#) [more »](#)

category: Patent Agents

London, UK

Search

What

Where

☐ Remember this location**Local**Search within: [1 mile](#) - [5 miles](#) - [15 miles](#) - [45 miles](#)**Patent Agents**

Great deals on Patent Agents
Shop on eBay and Save!
www.eBay.com

Invention and Idea Help

What to do when you have an idea
or invention. Free information.
www.theansweryouneed.com

Patent Attorneys

U.S. and Int'l Patent Applications
Fast and Affordable Service
www.premierpatents.com

Sp

**A. Brookes
Batchellor**
020 7253 1563

102-108 Clerkenwell Rd
London, EC1M 5SA
1.8 mi NE - Directions

References: brookesbatchellor.co.uk

B. ip21 Ltd
020 7645 8250

1 Cornhill
London, EC3V 3ND
1.9 mi NE - Directions

**C. Ablett &
Stebbing**
020 7935 7720

Caparo House 101-103 Baker St
London, W1U 6FQ
1.9 mi NW - Directions

References: absteb.co.uk

**D. Innovate -
Helping
Inventors**
020 7354 5640

61
Centa House Birkenhead St
London, WC1H 8BB
2.1 mi N - Directions

References: innovate-design.co.uk

**E. Gill Jennings &
Every**
020 7377 1377

Broadgate House
7 Eldon St
London, EC2M 7LH
2.2 mi NE - Directions

References: gje.com - [93 more »](#)

**F. Baron &
Warren**
020 7937 0294

19 South End
Kensington, London, W8 5BU
2.7 mi W - Directions

References: baron-warren.co.uk - [97 more »](#)

G. Jensen & Son
020 7613 0280

366-8 Old St
London, EC1V 9LT
2.7 mi NE - Directions

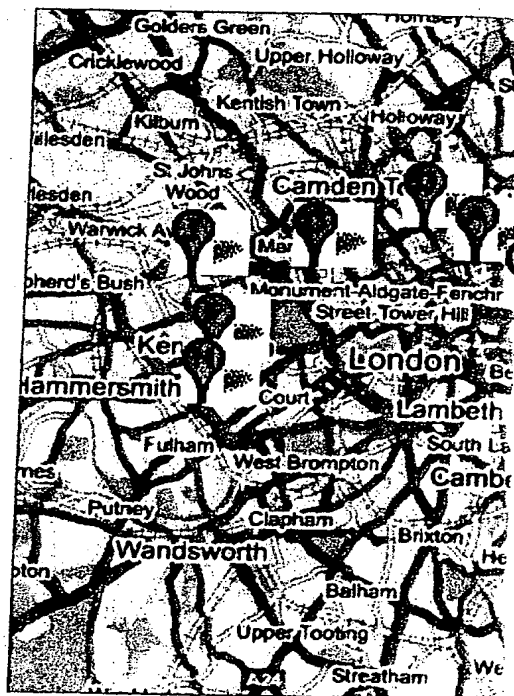
**H. T C Wood &
Co**
020 7370 6939

36 Earl's Court Square
Hammersmith and Fulham, SW5 9DQ
2.9 mi W - Directions

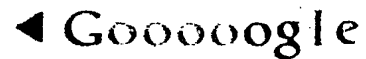
References: european-patent-office.org

I. P.J.H Stebbing
020 7221 2884

9 Shrewsbury Mews
London, W2 5PN
3.3 mi W - Directions

[View Larger Map](#)

References: itma.org.uk



Result Page: **Previous** [1](#) [2](#) [3](#) [4](#) [5](#)

category: Patent Agents

London, UK

Search

What

Where

☐ Remember this location

[Local Search Home](#) - [Google Home](#) - [Terms of Use](#) - [Local Search Help](#)

Business listings provided by [Yell.com](#)TM

Map data ©Crown copyright. License number 100026920
©2005 Google

ASSIGNMENT

WHEREAS we, WOOLFE, Austen John; LANGFORD, Alan; ALLEN, Jacquelin Yvonne; and ELLIOTT, Mark Clifford; have made an invention which is the subject of an international application under the Patent Cooperation Treaty ("PCT" patent application entitled PHARMACEUTICAL COMPOSITION, PCT/GB2003/002669 file 20 June 2003 ("Application"); and

WHEREAS NORTON HEALTHCARE LIMITED, a British company having its principal place of business at Ivax Quays, Albert Basin, Royal Docks, London E1 2QT, United Kingdom, wishes to acquire the entire interest in all our invention disclosed in such Application;

NOW, THEREFORE, for good and valuable consideration, the receipt of which is hereby acknowledged, we hereby sell, assign, transfer and set over unto Norton Healthcare Limited, its successors and assigns our entire right, title and interest in, to and under the Application, including all priority rights for other countries arising therefrom, all inventions therein disclosed, and any and all present or future patent applications to such inventions that may be filed in the United States or any foreign country, inclusive of, but not limited to, continuations, continuations-in-part, divisions, substitutions, re-examinations, reissues, international applications under the Patent Cooperation Treaty ("PCT"), United States provisional patent applications, certificates of addition, utility models, petty patents, as well as all other intellectual property related to the Application, inclusive of, but not limited to, supplementary protection certificates, copyrights, trademarks, and data package exclusivity rights; and any and all Letters Patent of the United States and of all foreign countries and all related patent term extensions which may be granted for Letters Patent with respect to the Application; all of the above to be held and enjoyed by Norton Healthcare Limited for its own use and enjoyment to the full end of the term or terms for which such Letters Patent and related intellectual property rights may be granted, as fully and entirely as the same would have been held and enjoyed by us had this Assignment and sale to Norton Healthcare Limited not been made.

For ourselves and for our heirs, successors and legal representatives, we covenant that no assignment, sale, agreement or encumbrance has been or will be made or entered into which would conflict with this Assignment.

For ourselves and for our heirs, successors and legal representatives, we further covenant and agree with Norton Healthcare Limited that upon request we and they will, without further consideration than that now paid, but at the expense of Norton Healthcare Limited, its successors or assigns: (i) execute original, provisional, substitute, continuation, divisional, continuation-in-part, re-examined, or reissued applications, amended specifications, or rightful declarations or oaths for such application; (ii) communicate to Norton Healthcare Limited any facts known to us or them relating to such inventions or the history thereof; (iii) execute preliminary statements and testify in any interference proceedings, litigation discovery proceedings and depositions, oppositions, cancellation proceedings, priority contests, public use proceedings, administrative agency proceedings, litigation and other court actions and the like; (iv) execute and deliver any application papers, affidavits, declarations, assignments, or other instruments; and (v) do all other acts which, in the opinion of counsel for Norton Healthcare Limited, may be necessary or desirable to secure the grant of Letters Patent and related intellectual property to Norton Healthcare Limited or its nominees, in the United States and in all other countries where Norton Healthcare Limited may desire to have such inventions, or any of them, patented, with specifications and claims in such form as shall be approved by counsel for Norton Healthcare Limited and to vest and confirm in Norton Healthcare Limited or its nominees the full and complete legal and equitable title to all such Letters Patent and related intellectual property.

IN WITNESS WHEREOF we have executed this assignment on the date indicated below.

Austen John WOOLFE

Date

First Witness

Second Witness

Signature

Signature

Printed Name

Printed Name

Address: _____

Address: _____

Alan LANGFORD

Date

First Witness

Second Witness

Signature

Signature

Printed Name

Printed Name

Address: _____

Address: _____

Jacqueline Yvonne ALLEN

Date

First Witness

Second Witness

Signature

Signature

Printed Name

Printed Name

Address: _____

Address: _____

Mark Clifford ELLIOTT

Date

First Witness

Second Witness

Signature

Signature

Printed Name

Printed Name

Address: _____

Address: _____

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

**POWER OF ATTORNEY
and
CORRESPONDENCE ADDRESS
INDICATION FORM**

Application Number

Filing Date

First Named Inventor

WOOLFE, Austen John

Title

Pharmaceutical Composition

Art Unit

Examiner Name

Attorney Docket Number

00303/US

I hereby appoint:

Practitioners associated with the Customer
Number:

OR



Practitioner(s) named below:

Name	Registration Number
HAY, Martin Alexander	39,459
STEINBERG, Michael	43,160
BROWDER, Monte	36,761

as my/our attorney(s) or agent(s) to prosecute the application identified above, and to transact all business in the United States Patent and Trademark Office connected therewith.

Please recognize or change the correspondence address for the above-identified application to:



The address associated with the above-mentioned Customer Number:

OR



The address associated with Customer Number:

024330

OR

Firm or
Individual Name

HAY, Martin Alexander

Address

Martin A. Hay & Co., 13 Queen Victoria Street

City

Macclesfield

State

Cheshire

Zip

SK11 6LP

Country

UNITED KINGDOM

Telephone

+44-1625-500057

Fax

+44-1625-500058

I am the:



Applicant/Inventor.

Assignee of record of the entire interest. See 37 CFR 3.71.
Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)**SIGNATURE of Applicant or Assignee of Record**

Signature		Date	
Name	Jacqueline Yvonne ALLEN	Telephone	
Title and Company			

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below.



*Total of 4 forms are submitted.

This collection of information is required by 37 CFR 1.31 and 1.33. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 3 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

**DECLARATION FOR UTILITY OR
DESIGN
PATENT APPLICATION
(37 CFR 1.63)**Declaration
Submitted
With Initial
Filing

OR

Declaration
Submitted after Initial
Filing (surcharge
(37 CFR 1.16 (e))
required)Attorney Docket
Number

00303/US

First Named Inventor

WOOLFE, Austen John

COMPLETE IF KNOWN

Application Number

Filing Date

Art Unit

Examiner Name

I hereby declare that:

Each inventor's residence, mailing address, and citizenship are as stated below next to their name.

I believe the inventor(s) named below to be the original and first inventor(s) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

PHARMACEUTICAL COMPOSITION

(Title of the Invention)

the specification of which



Is attached hereto

OR



was filed on (MM/DD/YYYY)

June, 20, 2003

as United States Application Number or PCT International

Application Number

PCT/GB2003/002669

and was amended on (MM/DD/YYYY)

(if applicable).

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment specifically referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56, including for continuation-in-part applications, material information which became available between the filing date of the prior application and the national or PCT International filing date of the continuation-in-part application.

I hereby claim foreign priority benefits under 35 U.S.C. 119(a)-(d) or (f), or 365(b) of any foreign application(s) for patent, inventor's or plant breeder's rights certificate(s), or 365(a) of any PCT International application which designated at least one country other than the United States of America, listed below and have also identified below, by checking the box, any foreign application for patent, inventor's or plant breeder's rights certificate(s), or any PCT International application having a filing date before that of the application on which priority is claimed.

Prior Foreign Application Number(s)	Country	Foreign Filing Date (MM/DD/YYYY)	Priority Not Claimed		Certified Copy Attached?	
					YES	NO
0214491.3	GB	June 22, 2002	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
0228111.1	GB	Dec 03, 2002	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>



Additional foreign application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto.

[Page 1 of 2]

This collection of information is required by 35 U.S.C. 115 and 37 CFR 1.63. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 21 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance completing the form, call 1-800-PTO-9199 and select option 2.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

DECLARATION — Utility or Design Patent Application

Direct all
correspondence to:



The address
associated with
Customer Number:

024330

OR



Correspondence
address below

Name

HAY, Martin Alexander

Address

Martin A. Hay & Co. 13 Queen Victoria Street

City

Macclesfield

State

Cheshire

ZIP

SK11 6LP

Country

UNITED KINGDOM

Telephone

+44-1625 500057

Fax

+44-1625 400058

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

NAME OF SOLE OR FIRST INVENTOR:



A petition has been filed for this unsigned inventor

Given Name (first and middle [if any])

Austen John

Family Name or Surname

WOOLFE

Inventor's Signature

Date

Residence: City

North Weald

State

Essex

Country

GB

Citizenship

GB

Mailing Address
31 Emberson Way

City

North Weald

State

Essex

Zip

CM16 6DL

Country

GB

NAME OF SECOND INVENTOR:



A petition has been filed for this unsigned inventor

Given Name (first and middle [if any])

Alan

Family Name or Surname

LANGFORD

Inventor's Signature

Date

Residence: City

Hoddesdon

State

Hertfordshire

Country

GB

Citizenship

NZ

Mailing Address
33a Briscoe Road

City

Hoddesdon

State

Hertfordshire

Zip

EN11 9DG

Country

GB



Additional inventors or a legal representative are being named on the supplemental sheet(s) PTO/SB/02A or 02LR attached hereto.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

DECLARATION**ADDITIONAL INVENTOR(S)**
Supplemental Sheet

Page 1 of 1

Name of Additional Joint Inventor, if any:		<input type="checkbox"/> A petition has been filed for this unsigned inventor	
Given Name (first and middle (if any))		Family Name or Surname	
Jacqueline Yvonne		ALLEN	
Inventor's Signature		Date	
Earlsfield Residence: City	London State	GB Country	GB Citizenship
13 Peartree Avenue			
Mailing Address			
Earlsfield City	London State	SW17 0JG Zip	GB Country
Name of Additional Joint Inventor, if any:		<input type="checkbox"/> A petition has been filed for this unsigned inventor	
Given Name (first and middle (if any))		Family Name or Surname	
Mark Clifford		ELLIOTT	
Inventor's Signature		Date	
Stoke Newington Residence: City	State	GB Country	GB Citizenship
40 Farleigh Road			
Mailing Address			
Stoke Newington City	State	N16 7TH Zip	GB Country
Name of Additional Joint Inventor, if any:		<input type="checkbox"/> A petition has been filed for this unsigned inventor	
Given Name (first and middle (if any))		Family Name or Surname	
Inventor's Signature		Date	
Residence: City	State	Country	Citizenship
Mailing Address			
City	State	Zip	Country

This collection of information is required by 35 U.S.C. 115 and 37 CFR 1.63. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 21 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet	1	of	1
-------	---	----	---

Complete If Known

Application Number	
Filing Date	
First Named Inventor	WOOLFE, Austen John
Art Unit	
Examiner Name	
Attorney Docket Number	00303/US

U. S. PATENT DOCUMENTS

[illegible]

FOREIGN PATENT DOCUMENTS

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T ⁶
		Country Code ³ Number ⁴ Kind Code ⁵ (if known)	MM-DD-YYYY			
	B1	WO01/89589	11.29.2001	Regents of the Univ of California		
	B2	WO03/006010	01.23.2003	Norton Healthcare Ltd		
	B3	WO01/66089	09.13.2001	GW Pharma Ltd		

Examiner Signature		Date Considered	
-----------------------	--	--------------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, Washington, DC 20231.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property
Organization
International Bureau



(43) International Publication Date
31 December 2003 (31.12.2003)

PCT

(10) International Publication Number
WO 2004/000290 A1

- (51) International Patent Classification⁷: **A61K 31/135**
- (21) International Application Number:
PCT/GB2003/002669
- (22) International Filing Date: 20 June 2003 (20.06.2003)
- (25) Filing Language: English
- (26) Publication Language: English
- (30) Priority Data:
0214491.3 22 June 2002 (22.06.2002) US
0228111.1 3 December 2002 (03.12.2002) US
- (71) Applicant (*for all designated States except US*): **NORTON HEALTHCARE LIMITED** [GB/GB]; Ivax Quays, Albert Basin, Royal Docks, London E16 2QT (GB).
- (72) Inventors; and
- (75) Inventors/Applicants (*for US only*): **WOOLFE, Austen, John** [GB/GB]; 31 Emberson Way, North Weald, Essex CM16 6DL (GB). **LANGFORD, Alan** [NZ/GB]; 33a Briscoe Road, Hoddesdon, Hertfordshire EN11 9DG (GB). **ALLEN, Jacqueline, Yvonne** [GB/GB]; 13 Peartree Avenue, Earlsfield, London SW17 0JG (GB). **ELLIOTT, Mark, Clifford** [GB/GB]; 40 Farleigh Road, Stoke Newington N16 7TH (GB).
- (74) Agents: **HAY, Martin, Alexander et al.**; Martin A. Hay & Co., 13 Queen Victoria Street, Macclesfield, Cheshire SK11 6LP (GB).
- (81) Designated States (*national*): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, OM, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.
- (84) Designated States (*regional*): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).
- Published:
— with international search report
- For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.*

(54) Title: **PHARMACEUTICAL COMPOSITION**

(57) Abstract: A pharmaceutical composition for administration as an aerosol, which comprises a cannabinoid, a propellant and an effective amount of a cough suppressant.

WO 2004/000290 A1

- 1 -

Pharmaceutical Composition

The present invention relates to a pharmaceutical composition. More particularly, it relates to an aerosol composition comprising a cannabinoid, to a metered dose dispenser containing the composition and to a method of administering the composition to a patient.

Cannabis is known to be useful in therapy, for example in the treatment of nausea and vomiting associated with cancer chemotherapy, anorexia associated with AIDS, pain, epilepsy, glaucoma, asthma and mood disorders. The principle active ingredient in cannabis is delta-9-tetrahydrocannabinol (delta-9-THC). A derivative of delta-9-THC, which possesses similar properties, is delta-8-tetrahydrocannabinol (delta-8-THC). Collectively, cannabis, delta-9-THC and derivatives thereof, such as delta-8-THC, are known as cannabinoids.

International patent application publication number WO 01/66089 and United States patent application publication number 2002/0031480 disclose aerosol compositions comprising a cannabinoid and a propellant for administration to patients using a metered dose dispenser. WO 03/006010, published on 23 January, 2003, also discloses aerosol compositions comprising a cannabinoid and a propellant for administration to patients using a metered dose dispenser.

It is reported in WO 01/66089 that administration of aerosol compositions comprising the cannabinoid, delta-9-THC, and a propellant to the lungs of patients caused the patients to cough. Applicant has encountered a similar problem when administering aerosol formulations comprising delta-8-THC. This cough reaction is undesirable, because it results in exhalation of much of the inhaled dose.

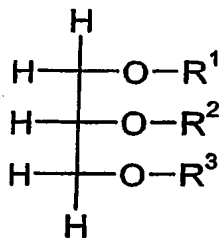
Surprisingly, it has now been found that by incorporating a sufficient amount of a certain kind of ingredient into the aerosol compositions, the cough reaction of patients is suppressed.

According to one aspect, therefore, the present invention provides a pharmaceutical composition for administration as an aerosol, which comprises a cannabinoid, a propellant and an effective amount of a cough suppressant.

5 Particularly good results have been obtained by incorporating medium chain triglycerides and propylene glycol diesters in a weight ratio of triglyceride to cannabinoid of at least 2:1, with the best results being obtained using weight ratios of at least 3:1 together with ethanol as a co-
10 solvent.

According to a preferred aspect, therefore the cough suppressant is a medium chain triglyceride or propylene glycol diester.

Medium chain triglycerides are well known in the
15 pharmaceutical formulation art, where they are mainly used in oral, parenteral and topical formulations. They are generally commercially available as mixtures of triglycerides of fatty acids consisting predominantly of octanoic (caprylic) and decanoic (capric) acid and may thus be represented by the
20 general formula



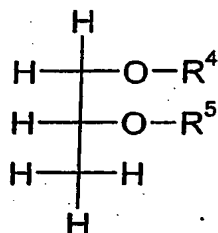
in which each of R^1 , R^2 and R^3 independently represents a group of formula $-\text{CO}-(\text{CH}_2)_n-\text{CH}_3$ in which n is an integer of from 6 to 8.

25 Examples of commercially available medium chain triglycerides are MIGLYOL™ 810 and 812, both caprylic/capric triglycerides available from CONDEA Chemie GmbH, Oleochemicals, Arthur-Imhausen-Str. 92, D-58433 Witten, Germany or CONDEA Vista Co., Commerce Dr., Cranford, NJ 07016,

- 3 -

United States, and CRODAMOL™ GTCC or CRODAMOL™ PC DAB 10(S), both caprylic/capric triglycerides, available from Croda Chemicals Ltd., Rawcliffe Bridge, Goole, East Riding, DN14 8PN.

5 Medium chain diesters of propylene glycol are generally commercially available as mixtures of diesters of fatty acids consisting predominantly of octanoic (caprylic) and decanoic (capric) acid and may thus be represented by the general formula



10

in which each of R^4 and R^5 independently represents a group of formula $-\text{CO}-(\text{CH}_2)_n-\text{CH}_3$ in which n is an integer of from 6 to 8.

An example of a commercially available medium chain
 15 diester of propylene glycol is MIGLYOL™ 840, a propylene glycol dicaprylate/dicaprate, available from CONDEA Chemie GmbH, Oleochemicals, Arthur-Imhausen-Str. 92, D-58433 Witten, Germany or CONDEA Vista Co., Commerce Dr., Cranford, NJ 07016, United States.

20 The cough suppressant may conveniently be present in a weight ratio of cough suppressant to cannabinoid of from 2:1 to 25:1, preferably 2.5:1 to 15:1, most preferably 3:1 to 10:1.

The cannabinoid may be, for example, an extract of
 25 natural cannabis, delta-9-THC, a derivative of delta-9-THC such as delta-8-THC, cannabidiol, or a mixture of any of these. Preferably it is delta-8-THC.

The propellant may be, for example, an alkane, such as butane, or a fluorocarbon, such as 1,1,1,2-tetrafluoroethane

(P-134a) or 1,1,1,2,3,3,3-heptafluoropropane (P-227).

Preferably it is P-134a.

The weight ratio of propellant to cannabinoid in the composition is conveniently in the range of from 10:1 to 10,000:1, such as from 250:1 to 10,000:1, preferably from 50:1 to 500:1.

The composition may further comprise one or more solid or liquid carriers or excipients, such as a pharmaceutically acceptable solvent, for example an alcohol such as ethanol, an essential oil, such as peppermint, or a major component thereof, such as menthol, or a solid bulking agent, such as lactose. Preferably, the composition is a solution.

The one or more carriers or excipients in the aerosol composition may conveniently comprise from 0 to 25 % by weight of the total composition.

It has been found to be advantageous to include ethanol in the composition. The ethanol may make up from 0.1% to 25% by weight of the formulation, preferably 1% to 25% of the formulation, more preferably 1% to 15%, most preferably from 3 to 5%. It has been found that when using high levels of ethanol, for example from 15 to 25% by weight, it is possible to use a lower ratio of cough suppressant to cannabinoid than is effective with low levels of ethanol. Furthermore, with high levels of ethanol, certain pharmaceutically acceptable aerosol surfactants, such as isopropyl myristate and Brij 30 (a lauryl polyoxyethylene ether), can function as cough suppressants. However, the best results have been obtained using medium chain triglycerides and propylene glycol diesters in compositions containing from 3 to 5% by weight ethanol.

In certain cases, administration of the cannabinoid has been found to be associated with undesirable after effects, such as a burning or tingling sensation in the throat, or a dry throat. It has been found that these effects may be reduced or eliminated by incorporating an essential oil in the

composition. Examples of essential oils include peppermint (of which the major constituent is menthol), eucalyptus (of which the major constituent is cineole), aniseed and cajeput. According to a preferred aspect, therefore, the composition
5 according to the present invention may further comprise an essential oil, such as peppermint, eucalyptus, aniseed or cajeput, or a major component thereof, such as methanol or cineole. Particularly good results have been obtained by incorporating menthol in compositions. The essential oil (e.g.
10 menthol) preferably comprises from 0.02 to 0.1% by weight of the composition. The weight ratio of essential oil to delta-8-THC is preferably in the range of from 0.05:1 to 0.4:1, more preferably 0.1:1 to 0.3:1.

The pharmaceutical composition according to the invention
15 may conveniently be administered to a patient using a metered dose dispenser, such as a metered dose inhaler. According to another aspect, therefore, the present invention provides a metered dose dispenser containing a pharmaceutical composition according to the invention. Preferably the metered dose
20 dispenser is adapted to provide a unit dose containing from 0.05 to 0.5 mg of the cannabinoid, preferably from 0.1 to 0.2 mg.

According to another aspect, the present invention provides a method of administering an aerosol composition
25 comprising a cannabinoid and a propellant to a patient, which comprises administering the cannabinoid and propellant with an effective amount of a cough suppressant.

According to another aspect, the present invention provides the use of an effective amount of a cough suppressant
30 in the manufacture of a medicament for suppressing coughing when an aerosol composition comprising a cannabinoid and a propellant is administered to a patient.

As used herein, the term patient refers to any human or non-human animal. Preferably the patient is a human.

- 6 -

The aerosol composition is conveniently administered by inhalation. However, it may be administered via a pulmonary, sub-lingual, nasal or buccal route. Thus, although the risk of provoking a cough is lower if an aerosol lacking a cough suppressant is administered via a sub-lingual, nasal or buccal route, it would be advantageous for patients to receive cannabinoid with a cough suppressant, in accordance with the present invention.

The following Examples illustrate the invention.

- 7 -

Example 1

Ingredient	Weight in mg
delta-8-THC	5.2 (0.1 mg dose)
P-134a	1606
5 Crodamol GTCC	15.9 (3.1:1 cough suppressant:cannabinoid)
Ethanol	42.7 (2.6% by weight)

Comparison Example 1

Ingredient	Weight in mg
10 delta-8-THC	6.1 (0.12 mg)
P-134a	1477
Crodamol GTCC	11.4 (1.9:1)
Ethanol	50.1 (3.3%)

15 Notes: A comparison between Example 1 and Comparison Example 1 shows that having a sufficient amount of Crodamol GTCC in the aerosol composition is important.

Example 2

20	Ingredient	Weight in mg
	delta-8-THC	5.0 (0.12 mg)
	P-134a	1220
	Crodamol PC DAB 10(S)	52 (10.4:1)
	Ethanol	0 (0%)

25

Example 3

	Ingredient	Weight in mg
	delta-8-THC	5.0 (0.23 mg)
	P-134a	656
30	Crodamol PC DAB 10(S)	15.5 (3.1:1)
	Ethanol	49 (7%)

- 8 -

Example 4

Ingredient	Weight in mg
delta-8-THC	5.1 (0.12 mg)
P-134a	1288
5 Crodamol PC DAB 10 (S)	15.1 (3:1)
Ethanol	100 (7.2%)

Example 5

Ingredient	Weight in mg
10 delta-8-THC	5.1 (0.12 mg)
P-134a	1274
Crodamol PC DAB 10 (S)	15.2 (3:1)
Ethanol	45.9 (3.5%)

15 Example 6

Ingredient	Weight in mg
delta-8-THC	5.2 (0.12 mg)
P-134a	1301
Crodamol PC DAB 10 (S)	16.8 (3.2:1)
20 Ethanol	144.3 (10%)

Example 7

Ingredient	Weight in mg
delta-8-THC	6 (0.15 mg)
25 P-134a	1128
Crodamol PC DAB 10 (S)	51 (8.5:1)
Ethanol	64 (5.4%)

Example 8

Ingredient	Weight in mg
30 delta-8-THC	10 (0.52 mg)
P-134a	581
Crodamol PC DAB 10 (S)	105 (10.5:1)
Ethanol	0 (0%)

- 9 -

Example 9

Ingredient	Weight in mg
delta-8-THC	20 (0.22 mg)
P-134a	2689
5 Crodamol PC DAB 10(S)	300 (15:1)
Ethanol	0 (0%)

Comparison Example 2

Ingredient	Weight in mg
10 delta-8-THC	5 (0.24 mg)
P-134a	634
Crodamol PC DAB 10(S)	5.5 (1.1:1)
Ethanol	49 (7.2%)

15 Comparison Example 3

Ingredient	Weight in mg
delta-8-THC	5.5 (0.13 mg)
P-134a	1253
Crodamol PC DAB 10(S)	13.5 (2.5:1)
20 Ethanol	101 (7.5%)

Example 10

Ingredient	Weight in mg
delta-8-THC	10 (0.19 mg)
25 P-134a	1340
Crodamol PC DAB 10(S)	58 (6.8:1)
Ethanol	151 (10.1%)
Micronized lactose	10

30 Example 11

Ingredient	Weight in mg
delta-8-THC	5.1 (0.12 mg)
P-134a	1239
Miglyol 810	17.7 (3.5:1)
35 Ethanol	49.2 (3.8%)

- 10 -

Example 12

	Ingredient	Weight in mg
	delta-8-THC	5.4 (0.09 mg)
5	P-134a	1796
	Miglyol 812	18 (3.3:1)
	Ethanol	41.1 (2.2%)

Example 13

10	Ingredient	Weight in mg
	delta-8-THC	10 (0.09 mg)
	P-134a	3207
	Miglyol 812	20.8 (2.1:1)
	Ethanol	193.4 (5.7%)

15

Example 14

	Ingredient	Weight in mg
	delta-8-THC	10 (0.1 mg)
	P-134a	3062
20	Miglyol 812	20.3 (2:1)
	Ethanol	261.5 (7.9%)

Comparison Example 4

	Ingredient	Weight in mg
25	delta-8-THC	5.6 (0.09 mg)
	P-134a	1788
	Miglyol 812	12.3 (2.2:1)
	Ethanol	41.9 (2.3%)

30 Comparison Example 5

	Ingredient	Weight in mg
	delta-8-THC	10.3 (0.1 mg)
	P-134a	3019
	Miglyol 840	20.8 (2:1)
35	Ethanol	124.7 (4%)

- 11 -

Notes: A comparison between Examples 13 and 14 and Comparison Examples 4 and 5 shows that increasing the percentage by weight of ethanol can compensate for a reduced cough suppressant/cannabinoid ratio.

5

Example 15

Ingredient	Weight in mg
delta-8-THC	25 (0.2 mg)
P-134a	3451
10 Miglyol 812	75 (3:1)
Ethanol	145 (4%)

Example 16

Ingredient	Weight in mg
15 delta-8-THC	52.4 (0.2 mg)
P-134a	6952
Miglyol 812	132.4 (2.5:1)
Ethanol	597.9 (7.9%)

20 **Example 17**

Ingredient	Weight in mg
delta-8-THC	6.6 (0.14 mg)
P-134a	1423
Miglyol 840	17.1 (2.6:1)
25 Ethanol	48.6 (3.3%)

Comparison Example 6

Ingredient	Weight in mg
delta-8-THC	4.97 (0.1 mg)
30 P-134a	1137
Ethanol	274.2 (19.4%)

- 12 -

Example 18

Ingredient	Weight in mg
delta-8-THC	25.4 (0.20 mg)
P-134a	3568
5 Miglyol 840	77.8 (3.1:1)
Ethanol	146.18 (3.9%)
Eucalyptus Oil	2.7 (0.07%)

Example 19

Ingredient	Weight in mg
10 delta-8-THC	24.8 (0.20 mg)
P-134a	3509
Miglyol 840	78.4 (3.1:1)
Ethanol	148.35 (4.1%)
15 Peppermint Oil	2.7 (0.07%)

Example 20

Ingredient	Weight in mg
delta-8-THC	12.46 (0.10 mg)
20 P-134a	3500
Miglyol 840	44.2 (3.5:1)
Ethanol	145 (4.0%)
Menthol	1.3 (0.04%, menthol: delta 8 0.1:1)

25 Example 21

Ingredient	Weight in mg
delta-8-THC	5.0 (0.10 mg)
P-134a	1380
Miglyol 840	14.1 (2.8:1)
30 Ethanol	63.2 (4.4%)
Menthol	0.69 (0.05%, 0.14:1)

- 13 -

Example 22

Ingredient	Weight in mg
delta-8-THC	2.6 (0.04 mg)
P-134a	1861
5 Miglyol 840	7.53 (2.9:1)
Ethanol	62.7 (3.3%)
Menthol	0.36 (0.02%, 0.14:1)

Example 23

Ingredient	Weight in mg
10 delta-8-THC	2.62 (0.05 mg)
P-134a	1512
Miglyol 840	8.08 (3.1:1)
Ethanol	62.1 (3.9%)
15 Menthol	0.71 (0.04%, 0.27:1)

Example 24

Ingredient	Weight in mg
delta-8-THC	5 (0.11 mg)
20 P-134a	990
Brij™ 30	28 (5.5:1)
Ethanol	249 (20%)

Example 25

Ingredient	Weight in mg
25 delta-8-THC	6 (0.12 mg)
P-134a	1068
Isopropyl myristate	31 (5:1)
Ethanol	271 (20%)

Example 26

Ingredient	Weight in mg
delta-8-THC	12 (0.1 mg/dose)
P-134a	3430
5 Miglyol 812	36 (3:1)
L-Menthol	1.51
Ethanol	302 (8%)

Example 27

Ingredient	Weight in mg
10 delta-9-THC	4.99
P-134a	1514.9
Miglyol 812	17.38
Ethanol	63.7

15

Example 28

Ingredient	Weight in mg
Cannabidiol	11.9
P-134a	1814.0
20 Miglyol 812	30.3
Ethanol	130.3

The effect of administering the compositions of the Examples and Comparison Examples on patients was investigated as follows:-

The ingredients were filled in standard glass vials with a normal valve and seals. The completed units were put in a standard actuator and primed. Then one puff of each was taken in the normal manner by the volunteer.

The compositions of the Examples were found to produce no cough, whereas those of the Comparison Examples were found to produce a spontaneous cough within 2-3 seconds.

An experiment was also conducted to investigate whether the cough suppressant and cannabinoid could be administered sequentially. This is described below.

5

Ingredient	First Dose	Second Dose
	Weight in mg	Weight in mg
delta-8-THC	0	4.8 (0.01mg)
P-134a	1540.4	1502.0
10 Miglyol 812	25.2	
Ethanol	65.4 (4.1%)	62.3 (4.0%)
Eucalyptus Oil	0	18.6

The first dose, containing Miglyol 812, was inhaled twice,
15 then the second dose was inhaled. The ratio of Miglyol 812:
delta-8-THC inhaled was 10.5:1. A spontaneous cough was
provoked after 5 seconds. This experiment shows that the
cough suppressant needs to be administered with the
cannabinoid.

20

It will be understood that the Examples have been provided to
illustrate the invention. The invention is not limited to
compositions using the particular cough suppressants described
in these Examples or particularly described herein. Following
25 the teachings herein about how the cough reflex may be
suppressed in aerosol formulations containing a cannabinoid
and a propellant, those skilled in the art should readily be
able to identify other cough suppressants.

Claims

1. A pharmaceutical composition for administration as an aerosol, which comprises a cannabinoid, a propellant and an effective amount of a cough suppressant.
2. A composition as claimed in Claim 1, which is a solution.
3. A composition as claimed in Claim 1 or Claim 2, in which the weight ratio of cough suppressant to cannabinoid in the composition is in the range of from 2:1 to 25:1.
4. A composition as claimed in Claim 3, in which the weight ratio of cough suppressant to cannabinoid in the composition is in the range of from 2.5:1 to 15:1.
5. A composition as claimed in Claim 4, in which the weight ratio of cough suppressant to cannabinoid in the composition is in the range of from 3:1 to 10:1.
6. A composition as claimed in any one of Claims 1 to 5, in which the cough suppressant is a medium chain triglyceride or propylene glycol diester.
7. A composition as claimed in any one of Claims 1 to 6, in which the propellant is 1,1,1,2-tetrafluoroethane.
8. A composition as claimed in any one of Claims 1 to 7, in which the cannabinoid is delta-8-THC.
9. A composition as claimed in any one of Claims 1 to 8, which further comprises ethanol.

- 17 -

10. A composition as claimed in Claim 9, which comprises from 1 to 15% by weight of ethanol.
11. A composition as claimed in Claim 10, which comprises 5 from 3 to 5% by weight of ethanol.
12. A composition as claimed in any one of Claims 1 to 11, which further comprises an essential oil or a major component thereof.
- 10 13. A composition as claimed in Claim 12, in which the essential oil or a major component thereof is menthol.
14. A composition as claimed in Claim 13, which comprises 15 from 0.02 to 0.1% by weight of menthol.
15. A metered dose dispenser, which contains a pharmaceutical composition as claimed in any one of Claims 1 to 14.
- 20 16. A metered dose dispenser as claimed in Claim 16, which is a metered dose inhaler.
17. A metered dose dispenser as claimed in Claim 15 or Claim 16, which is adapted to provide a unit dose containing from 25 0.1 to 0.2 mg of cannabinoid.
18. The use of an effective amount of a cough suppressant in the manufacture of a medicament for suppressing coughing when an aerosol composition comprising a cannabinoid and a 30 propellant is administered to a patient.
19. A method of administering an aerosol composition comprising a cannabinoid and a propellant to a patient, which

comprises administering the cannabinoid and propellant with an effective amount of a cough suppressant.

STATEMENT OF EMPLOYMENT PARTICULARS

DATE ISSUED

14 November 2001

NAME OF EMPLOYER

NORTON HEALTHCARE LIMITED
ALBERT BASIN
ROYAL DOCKS
LONDON
E16 2QJ ("the Company")

NAME OF EMPLOYEE

Jacqueline Allen

**DATE OF COMMENCEMENT OF
THESE TERMS AND CONDITIONS**

1st December 2001

**DATE OF CONTINUOUS
EMPLOYMENT WITH THE COMPANY**

As above

TYPE OF CONTRACT

Fixed Term

JOB TITLE

You will be employed as a Synthetic Chemist, within the Research & Development Department reporting to the Head of New Product Development ("the Manager"). Your title conveys the nature of the work that you are required to perform, however, when considered appropriate or necessary by the Company you may be required to report to another manager or carry out such other duties as are considered to be within your skill and competence.

You will be expected to undertake your work for any Company in the Norton Group when given reasonable notice. Where applicable, the Company's Relocation Policy will apply. Please refer to Appendix 2 for the definition of Norton Group.

RATE OF PAY

Your salary will be £24,000 per annum.

This salary will be paid pro rata according to the length of time in employment.

Salary will be paid each calendar month on or around the 21st day of each month by Bank Giro Credit. However you may be paid at the end of the first calendar month in which you work. This covers the payment from the date of commencement of employment to the end of the month.

You must always maintain a suitable bank or building society account into which payment can be made, and provide up-to-date written details to the Human Resources Department.

ADDITIONAL PAYMENTS

If you are required to provide call-out cover, you will receive a payment in accordance with the Company's Call Out Policy.

At the end of your two year contract you will be eligible for a 10% bonus.

HOURS OF WORK

Your normal working week is 35 hours, and your hours of duty will be determined by your Manager. This is exclusive of a one hour unpaid lunch break per day. You will, however, be expected to work such other hours as are necessary for the successful completion of your duties.

Flexible working arrangements operate within the Company. Your Manager will discuss the operation of this within your department.

You agree for the purposes of the Working Time Regulations 1998 that the provision imposing a maximum working week of 48 hours will not apply to your employment. However, you have the right to withdraw your agreement to this at any time by giving the Company one month's written notice of your intention to do so.

PLACE OF WORK

Your normal place of work is the Company's European Headquarters at Royal Docks, Albert Basin, London E16 2QJ.

The Company reserves the right to change your place of work in order that you might more effectively carry out your duties. You will be given one month's written notice of any such change.

This is a fixed term appointment initially for a period of two years depending on the needs of the business.

ANNUAL LEAVE

Your annual leave entitlement in a full year is 25 days. The leave year runs from 1st January to 31st December.

Employees joining or leaving the Company part way through the leave year will receive the appropriate proportion of that year's entitlement according to the number of completed months worked.

PRO RATA ANNUAL LEAVE ENTITLEMENT	
COMPLETED MONTHS	DAYS
One	2
Two	4
Three	6
Four	8
Five	10
Six	12.5

Seven	14.5
Eight	17
Nine	19
Ten	21
Eleven	23

The entitlements shown apply to employees who work a 5 day week. For employees who work less than 5 days per week, entitlement is calculated on a pro rata basis.

In addition to your annual leave entitlement, you are entitled to 8 statutory Public Holidays.

When a public holiday falls on a Saturday or Sunday, the Company will designate another day as a holiday. The Company may, however, require certain employees to work on a public holiday to meet essential business needs. In such circumstances the Company will endeavour to provide adequate notice.

Annual leave must be agreed in advance by your Manager and taken at the discretion of the Company in accordance with the provisions of the Company Leave Policy.

Notwithstanding the above, the Company may designate up to 5 days annual leave as Company holidays.

Where the full annual leave entitlement cannot be taken within the leave year a maximum of 3 days may be carried over into the following leave year subject to the agreement of your Manager. There is no provision for payment in lieu of annual leave not taken.

PROBATIONARY PERIOD

In order to provide both you and the Company an opportunity to assess your suitability for the position, it is our policy to regard the first six months of your employment as a probationary period. The Company reserves the right in exceptional circumstances to extend your probationary period following this assessment. At any time during the first four weeks of such probationary period either you or the Company may terminate your employment with one week's notice. During the remainder of your probationary period either you or the Company may terminate your employment by giving one month's notice in writing.

PENSIONS

The Company operates a contributory pension scheme which is open to employees under the age of 65 who have completed 6 months service. Further details of the pension scheme are contained in the Group Pension Scheme booklet.

EXPENSES

If you are issued with a Corporate Charge card for the payment of legitimate business expenses, you will be bound by the rules contained in both the Travel and Business Expenses Policy and the Card Issuer Policy.

MEDICAL INSURANCE

You will be entitled to participate in the Company's contributory PPP scheme whilst employed with the Company, subject to the terms and conditions of the provider and the provider accepting you on the normal terms and rates enjoyed by the Company.

LIFE ASSURANCE

Non contributory Life Assurance is offered to non pension scheme members subject to the terms and conditions of the provider and them accepting you on the normal terms and rates agreed by the Company.

COMPANY SICK PAY

You will be eligible to participate in the Company's sick pay scheme after successful completion of your probationary period.

Sick pay is at the sole discretion of the Company, and is subject to your compliance with the provisions of the Absence Policy, and any statutory obligations.

The Company will pay you at your basic rate of pay, exclusive of overtime according to your length of service as described in the table below:-

Length of service	Full Pay	Half Pay
0-6 months	SSP Only	Nil
6-12 months	5 days	5 days
12-24 months	1 month	1 month
24 - 36 months	2 months *	2 months *
36 months +	3 months *	3 months *

* Payment of these additional periods will be considered upon request in exceptional circumstances.

Full details of the terms and conditions of the Company sick pay scheme are set out in the Employee Handbook

DISCIPLINARY AND GRIEVANCE PROCEDURES AND APPEALS

The primary aim of the Company is to promote open working relationships and to help employees whose performance or conduct falls below Company requirements.

Where differences occur the Company will consider the views of each party in an effort to resolve issues locally. Where this is not possible the provisions of the Company's Disciplinary Procedure and Grievance Procedure contained in the Employee Handbook will apply.

If you are dissatisfied with any formal disciplinary or grievance decision you have the right to appeal. The Appeal must be made in writing to the Head of Human Resources, or where the Head of Human Resources has conducted the hearing, to

the Group Human Resources Director, stating the reason for appeal. Notice of appeal must be received in writing within 10 working days of the disciplinary or grievance decision.

Please refer to the Disciplinary and Grievance Procedures for further details.

SMOKING

The Company provides a smoke-free work environment and you will be required to comply with the Company's No Smoking Policy.

SECURITY PASSES

The wearing of the identification security pass is Company policy and forms part of your conditions of service. If you persistently fail to produce your identification security pass or lose it, the matter will be dealt with under the Company's disciplinary procedure and could result in disciplinary action.

DRESS CODE

If you are provided with a Company uniform you will be required to wear it at all times whilst on duty. Provisions on dress code may be found in the Company's Dress Code Policy.

HEALTH AND SAFETY

As a result of the 1974 Health and Safety at Work Act, you should know of the Company's Safety Policy. You must take reasonable care for the health and safety of yourself and of other people who could be affected by what you do or fail to do. It is therefore important that you know and understand the responsibilities you have for safety, health and welfare, including the wearing and use of protective clothing and safety equipment. On taking up appointment you will receive safety induction training. You must comply with the Company's General Statement of Safety Policy and all safety policies and procedures.

RESTRICTION ON COMPETITION

The intention of this clause is to provide an equitable balance to both individuals and the Company and is not intended to unreasonably restrict employees. Nevertheless it's purpose is to protect the interests of the business. Please refer to Appendix 1.

INVENTIONS

If during your employment with the Company you make or discover any invention or design, or make any improvement upon any existing invention, literary or artistic work including any computer programme or design, which relates to your employment, this shall belong to the Company and must be immediately disclosed to your Manager. You shall at the Company's request and expense take all the necessary steps to ensure that all rights shall, subject to the provisions of the Patents Act 1977, become the property of the Company or its nominee.

TIME AND ATTENTION

You will devote the whole of your time and attention to the duties of your employment and will not be engaged or concerned in any other employment or business activities which may have an impact on your ability to execute your duties, or could conflict with the interests of the Company.

In the event that you wish to consider any other employment or business activities outside your working hours, you are obliged to notify the Company in writing. The Company will provide written authorisation where it is agreed that such employment or activities are considered acceptable.

CONFIDENTIALITY

You shall not at any time during your employment or at any time thereafter, without the prior written consent of the Company, whether on your own behalf or as an employee, partner or agent of any other person from the Company, disclose or allow to be disclosed or use (except in the performance of your duties hereunder) any trade secrets or confidential information concerning the business dealings, affairs or conduct of the Company or the Norton Group or any of its suppliers, customers or clients or any other similar matters which may come to your knowledge in the course of your employment.

Confidential information includes (but is not limited to, and may include any other information as is deemed to be such by the Company from time to time) details about the Company's sale strategies, marketing plans, pricing and discount policies, remuneration of employees, details of clients and suppliers, product formulations, product specifications, product forecasts, licences and financial and accounting data. Confidential information may also include information which has been made available to the Company by a third party which the Company is obliged to keep confidential.

You will if requested by the Company at any time in the employment contract or upon the giving or receiving of notice or upon termination return or delete all confidential information from any computer disks, tapes or other reusable material and return or destroy all other documents and tangible items which contain or refer to any confidential information on trade secrets which are in your possession or under your control and you will not retain copies or extracts therefrom.

The above restrictions cease to apply if disclosure is ordered by a Court or Government or other authority or regulatory body or in relation to trade secrets or other confidential information which has come into the public domain (otherwise than through an unauthorised disclosure by you or a third party).

NOTICE PERIOD

You are employed on a fixed term contract which is expected to terminate not later than 31 December 2003 depending on the needs of the business. Your employment can be terminated by either you or the Company by giving one months notice.

If, on termination of this contract of employment you have any outstanding financial commitment to the Company (e.g. loan, training expenses, excess annual leave, relocation expenses), then you agree to the Company recovering direct from your final salary an amount up to the total sum owed.

You are responsible for repaying any remaining balance on terms agreeable to the Company.

GARDEN LEAVE

If you or the Company give notice to terminate your employment the Company may decide to place you on 'Garden Leave' for all or part of your notice period. During this time the Company would be under no obligation to provide any work for you and may exclude you from its premises. It may also disconnect any Remote Access Server and restrict your access to the Company's computer systems, its employees, customers and suppliers for any purpose related to the Company's business.

You will not work for any other firm or company during your normal working hours while you are on garden leave and you should remain available to work within 24 hours notice as referred to in the Time and Attention clause. During the period of 'Garden Leave' you will continue to receive your salary and all other contractual benefits, subject to deductions for tax and national insurance etc.

WORKING OVERSEAS

Under your present employment you may be required from time to time to work outside the UK in the normal course of business.

PROTECTION OF PERSONAL DATA

It is important that all employees are aware that under the terms of the Data Protection Act 1998 (as may be amended replaced or superseded from time to time), individuals as well as the Company are liable to prosecution for the unauthorised use and disclosure of personal data held on a computer or word processor.

If at any time you are required to access personal data it is your responsibility to ensure that you have the authority to process and/or disclose that data.

CHANGE TO TERMS

The Company reserves the right to amend any terms and conditions of employment in the interests of it's efficient running. When any terms and conditions are changed, you will be given one month's written notice of such amendments. Minor changes of detail may be made from time to time and will be effected by a general notice to employees. Failure to comply with any of the clauses contained in this contract could result in disciplinary action.

The Company reserves the right in it's sole discretion to review or amend any policy referred to from time to time.

APPENDIX 1

RESTRICTION ON COMPETITION

The following words shall have the following meanings in this Clause.

"Termination Date" shall mean the date of termination of your employment with the Company.

"Relevant Period" shall mean the 12 month period ending with the Termination Date.

"Restricted Customer" shall mean any person, firm, company or at any time in the Relevant Period a customer or client of the Company or Norton Group.

"Prohibited Business" shall mean any business or activity carried on by the Company or Norton Group at the Termination Date or any time in the Relevant Period in which you shall have been directly concerned in the course of your employment at any time in the Relevant Period.

"Protected Supplier" shall mean supplier of the Company or Norton Group in relation to the Prohibitive Business within which you shall have had material dealings in the course of your employment during the Relevant Period.

You will have dealings in the course of your employment with the customers, clients, suppliers, employees, confidential information and trade secrets of the Company or Norton Group. In order to protect the goodwill of the Company or Norton Group, you agree without prejudice to any other duty implied by law or equity, that during your employment and thereafter a period of 12 months after the Termination Date, that you shall not, without the prior written consent of the Company, in any capacity whether directly or indirectly, through any other person firm or company so as to compete with the Company or Norton Group:

- (a) canvass or solicit or by any other means seek to conduct Prohibited Business with any Restricted Customer with whom you shall have had any material dealings in the course of your duties in the Relevant Period.
- (b) conduct Prohibited Business with any Restricted Customer with whom you shall have had any material dealings in the course of your duties in the relevant Period.
- (c) directly or indirectly seek to entice away from the Company or Norton Group or otherwise solicit or interfere with the relationship between the Company or Norton Group and any Protected Supplier.

(d) solicit entice or induce directly or indirectly any director, manager, senior employee, sales person with whom you have had dealings during the Relevant Period to leave the Company or Norton Group and become employed by any person firm or company which is in competition to the business of the Company or Norton Group whether or not such person would commit a breach of contract by reason of leaving and you will not approach any such director, manager, senior employee or sales person with whom you have dealings during the Relevant Period for such purpose or authorise or knowingly approve the taking of such actions by any other person firm or company.

(e) Each of the obligations contained in sub-clauses (a) – (d) above shall be construed as separate and severable obligations. In the event that any such obligations shall be found void, but would be valid if some part were deleted or the period or area of application reduced, such obligation shall apply with such modification as may be necessary to make it valid and effective.

APPENDIX 2

NORTON GROUP

The expression Norton Group is defined as any company or companies for the time being which is:-

- (a) a subsidiary of the Company
- (b) a company (other than a subsidiary) in which the Company holds shares whether directly or indirectly;
- (c) a holding company of the Company e.g. IVAX; or
- (d) any other company in which a holding company of the Company holds shares whether directly or indirectly.

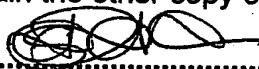
The words "subsidiary" and "holding company" have meanings respectively attributed to them in Section 736 of the Companies Act 1985 (as amended)

Confirmation of your employment will be subject to the receipt of medical clearance by our Company Doctor. Please ensure that you complete and return the enclosed forms immediately.

References will be taken up and your employment will be conditional upon receipt by the Company of satisfactory references. If the Company does not receive satisfactory references then the offer of employment to you may be withdrawn or your employment terminated (as the case may be) by immediate written notice.

Enclosed are two original copies of your contract. Please would you confirm your acceptance to the above Terms and Conditions, Employment Handbook and IVAX code by signing one copy and returning it to the Human Resources Department as soon as possible. Please retain the other copy of your contract for your records.

Authorised by:



Position:

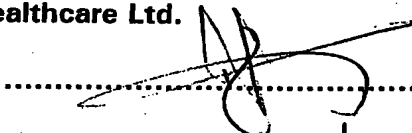
HR Adviser

Date:

12/11/01

I hereby agree and accept that the preceding provisions of this Statement of Employment Particulars in conjunction with the current edition of the Employee Handbook, and the IVAX Code of Conduct comprise my terms and conditions of employment with Norton Healthcare Ltd.

Signed




Date

18/11/01

Filed on behalf of Norton Healthcare Limited
Deponent: D. W. Cottam
First Affidavit of the Deponent
Date of Swearing: 10 April 2006

IN THE MATTER of United States Patent Application Number 10/516,943

EXHIBIT "DC5" TO THE AFFIDAVIT OF DAVID WILLIAM COTTAM



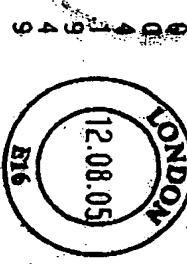
DAVID WILLIAM COTTAM



PRACTISING SOLICITOR

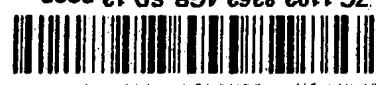
Royal Mail
Express Delivery

Return Address
Ivax Pharmaceuticals
Royal Docks
London
E16 2QJ



POSTAGE PAID
0385
PB504429J
GREAT BRITAIN

ZC 1192 8362 4GB SD 12 noon



Postcode

to

Name

~~M. Kneelme Allen~~

Address

~~14 Leathers Avenue~~

~~Leatherhead~~

~~London~~

Postcode

EW17 10JG



ensure all information below is correct and in full

return to the Royal Mail

if you are unsure, your nearest Royal Mail

branch will be able to help you

Royal Mail

☒ we were unable to deliver this item because

☒ addressee has gone away

☐ no answer

☐ address incomplete

☐ address inaccessible

☐ addressee unknown

☐ refused

☐ not called for

☐ no such address in

date 3/9

badge number

initials

P396097302343


Sender's name and address

IVAX PHARMACEUTICALS

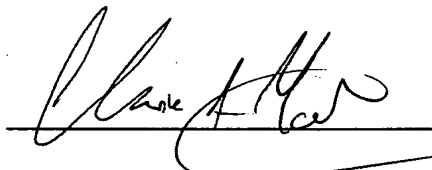
Filed on behalf of Norton Healthcare Limited
Deponent: D. W. Cottam
First Affidavit of the Deponent
Date of Swearing: 10 April 2006

IN THE MATTER of United States Patent Application Number 10/516,943

EXHIBIT "DC6" TO THE AFFIDAVIT OF DAVID WILLIAM COTTAM



DAVID WILLIAM COTTAM


PRACTISING SOLICITOR

5/9/06 Note of phone call to Jackie Allen

phoned Jackie, No reply

5/9/06 D. Wright

Ex. B

Filed on behalf of Norton Healthcare Limited
Deponent: A. Cunningham
First Affidavit of the Deponent
Date of Swearing: 14 June 2006
Exhibits: AC1-43

IN THE MATTER of United States Patent Application Number 10/516,943

AFFIDAVIT OF ANNETTE CUNNINGHAM

I, ANNETTE CUNNINGHAM, of Hurst Cottage, Sutton, Pulborough, West Sussex, RH20 1PL, United Kingdom, New Zealand Patent Attorney, MAKE OATH and say as follows:

1. I am the European Director-Intellectual Property for Norton Healthcare Limited (Norton) and I make this affidavit in support of Norton's United States patent application number 10/516,943 entitled "Pharmaceutical Composition". In so far as the content of this affidavit is within my personal knowledge it is true, and so far as it is not within my personal knowledge it is true to the best of my knowledge information and belief.
2. On 15 March I received an email from Jacqueline Allen asking me about the terms of the assignment (appended as Exhibit AC1).
3. On 9 May 2005, following requests made to Jacqueline Allen's former colleagues (Sophia Chew, John Woolfe and Stephen England) I received an email from Stephen England that contained Jacqueline Allen's mobile phone number (appended as Exhibit AC2).
4. On or about 10 May 2005 I left a voice mail message on Jacqueline Allen's cell phone telling her that I would discuss any questions she had about the assignment. I never received a reply to this voice mail message.
5. On 31 May 2005 I sent an email to Jacqueline Allen's work email address stating that I would discuss any questions she had regarding signing the documents (appended as Exhibit AC1).
6. On 1 June 2005 I had a telephone conversation with Jacqueline Allen. She informed me that she had been advised not to sign. I discussed her concerns with her at length in an attempt to persuade her there was no disadvantage to her signing the document. She decided to consider the matter and get back to me. I made a telephone note of this conversation that is appended as Exhibit AC3.

7. On 21 June 2005 Jacqueline Allen sent an email to me requesting that IVAX (the trading name of Norton Healthcare Limited) pay in advance legal costs for external legal advice regarding the documents my PA Simone Frankel had sent her (appended as exhibit AC1).

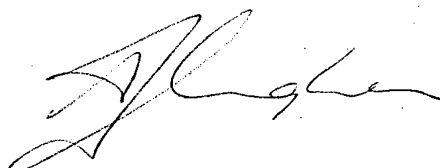
8. On 22 June 2006 I replied to Jacqueline Allen's email stating that Dr. David Cottam, Norton Healthcare Limited's Intellectual Property Counsel, would be in touch with her and that we could not pay external legal fees (appended as Exhibit AC1).

Sworn at ROITER LUKER
CHANCERY LANE
LONDON

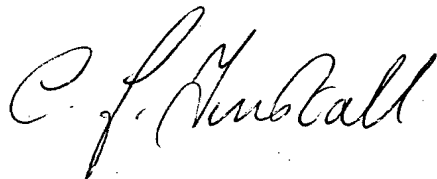
this 14th day of
June 2005

Before me,

CLARE FRANCES TUNSTALL
SOLICITOR



Signature of Deponent making the Affidavit

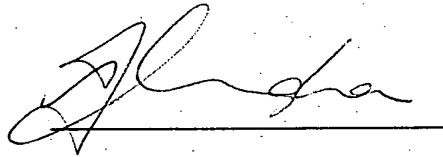
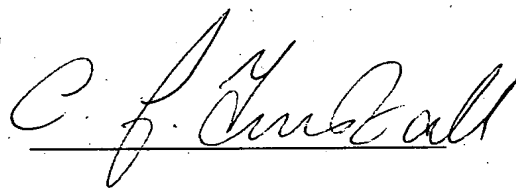


Signature of Authorised Witness

Filed on behalf of Norton Healthcare Limited
Deponent: A. Cunningham
First Affidavit of the Deponent
Date of Swearing: 14 June 2006

IN THE MATTER of United States Patent Application Number 10/516,943

EXHIBIT "AC 1" TO THE AFFIDAVIT OF ANNETTE CUNNINGHAM


ANNETTE CUNNINGHAM
PRACTISING SOLICITOR



Annette
Cunningham/NHC/IVAX
22/06/2005 16:23

To JAllen@pharmalytic.com
cc David Cottam/London/UK/IVAX,
bcc
Subject Re: Pharmaceutical Composition Patent application number
PCT/GB2003/002669

Dear Jackie,

I am very sorry you feel unable to sign the document after our discussion, but it seems that you are not likely to be persuaded by further discussion..I should point out that refusal of an inventor to sign an assignment document for work conducted under the circumstances of your employment are very unusual.

I am therefore passing this on to David Cottam, our barrister who is prosecuting the patent application. He has found that there are alternative provisions which allow for refusal of an inventor to sign and he can explain the situation to you.

He will be in touch with you soon. Please feel free to discuss this further with either of us if you wish. However, clearly we cannot meet any external legal fees on your behalf.

Kind regards.

Annette

annette.cunningham@ivax.co.uk
Tel: 020 7540 7076
Fax: 020 7540 7029
JAllen@pharmalytic.com



JAllen@pharmalytic.com
21/06/2005 13:42

To Annette.Cunningham@ivax.co.uk
cc
Subject Re: Pharmaceutical Composition Patent application number
PCT/GB2003/002669

Dear Annette,

As promised I would like to advise you of my decision with regards to the signing of the subject matter. During our conversation you advised me that I am legally bound to sign the document upon request by IVAX. You also explained, with regard to my query that the patent says that we are being paid for the rights, that we are selling it and we have received consideration, that this refers solely to payment that was received for work carried out whilst under contract to IVAX. Unfortunately, as I do not have any experience in this field and are no longer contracted to IVAX I do not feel I am in the position to be able to sign documentation at this time. Should IVAX undertake to pay in advance legal costs so I am able to take professional advice on this matter, I would not hesitate to be of assistance. I trust you understand my need for precaution.

Kind Regards

Jackie

Annette Cunningham

<Annette.Cunningham@ivax.co.uk>

31/05/05 11:49

To: JAllen@pharmalytic.com

cc:

Subject: Re: Pharmaceutical Composition Patent application
number PCT/GB2003/002669

Dear Jackie,

Further to my message on your mobile phone, please would you call me to discuss any questions you may have regarding signing the document you have been sent.

I look forward to hearing from you.

Kind regards.

Annette

annette.cunningham@ivax.co.uk

Tel: 020 7540 7076

Fax: 020 7540 7029

JAllen@pharmalytic.com

15/03/2005 11:14

To: annette.cunningham@ivax.co.uk

cc:

Subject: Pharmaceutical Composition Patent application number PCT/GB2003/002669

This note confirms that this email message has been swept by Mimesweeper for the presence of computer viruses and to ensure that it conforms to IVAX Policy.

Hi Annette,

Regarding the Pharmaceutical Composition Patent that requires signatures upon reading the assignment is it not saying that we are being paid for the rights, that we are selling it and we have received consideration. This is not correct. Can you please explain why this is written into the assignment.

Thanks

Jackie

Visit us at <http://www.pharmalytic.com>

Confidentiality

The information contained within this e-mail and any attachment(s) sent by Pharmalytic Limited is confidential and is intended only for the named recipient. If you are not the intended recipient please notify us by telephone immediately on +44 (0)1689 898192 or return it to us by e-mail quoting the name of the sender and the intended addressee. Please do not make copies and delete it from your system.

Reported Data

It is the policy of this Company that analytical data transmitted electronically via e-mail should be considered as unchecked, unapproved and is yet to conform fully to our Quality procedures for the release of such data.

Viruses

It is the responsibility of the recipient to ensure that this e-mail and any attachments are free of viruses. Viruses and compromises of security are inherent risks in relation to e-mail and therefore, we do not, to the extent permitted by law, accept any liability (whether in contract, negligence or otherwise) for any virus infection and/or external compromise

This email has been scanned for all viruses by the MessageLabs SkyScan service

IMPORTANT NOTICE

This communication contains information which is confidential and may also be privileged. It is for the exclusive use of the intended recipient(s).

If you are not the intended recipient(s) please note that any distribution, copying or use of this communication or the information in it is strictly prohibited. If you have received this communication in error please notify us immediately by email or by telephone +44(0) 20 7 540 7000 and then delete this email and any copies of it.

This communication and any communication received by or on behalf of IVAX Pharmaceuticals UK or from or on behalf of anyone else from this email address may be monitored by our email or other monitoring software or inspected by us. You consent to such monitoring and inspection by reading and/or saving this communication or communicating with this email address or any email address @ivax.co.uk.

This footnote also confirms that this email message has been swept by MIMESweeper for the presence of computer viruses.

Visit us at <http://www.pharmalytic.com>


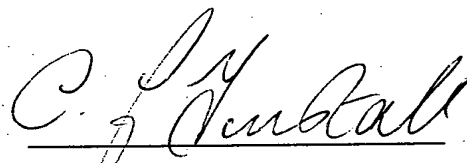
Confidentiality



Filed on behalf of Norton Healthcare Limited
Deponent: A. Cunningham
First Affidavit of the Deponent
Date of Swearing: /4 June 2006

IN THE MATTER of United States Patent Application Number 10/516,943

EXHIBIT "AC 2" TO THE AFFIDAVIT OF ANNETTE CUNNINGHAM


ANNETTE CUNNINGHAM
PRACTISING SOLICITOR

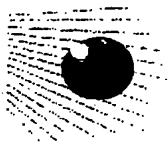
1/6/05

Spoke to Jackie Allen

She has been advised not to sign!

I have tried to persuade her to do
so. She will get back to me.

AK



Annette
Cunningham/NHC/IVAX
09/05/2005 12:46

To Simone Frankel/NHC/IVAX@IVAX
cc
bcc
Subject Fw: Jackie Allen

Annette Cunningham
European Director - Intellectual Property
IVAX Pharmaceuticals UK
Albert Basin, Royal Docks, London E16 2QJ, UK

annette.cunningham@ivax.co.uk
Tel: 020 7540 7076
Fax: 020 7540 7029

— Forwarded by Annette Cunningham/NHC/IVAX on 09/05/2005 12:46 —

Stephen
England/NHC/IVAX
09/05/2005 12:29

To Annette Cunningham/NHC/IVAX@IVAX
cc
Subject Jackie Allen

Annette,
Please find Jackies contact number below.
Regards
Steve

JACKIE ALLEN'S MOBILE NUMBER 07956 824 225

Stephen England
Principal Scientist (New Product Development)
Ivax Pharmaceuticals UK Ltd
Aston Lane North,
Whitshouse Vale Industrial Estate,
Preston Brook
Runcorn
Cheshire
WA7 3FA
Telephone 01928 707800 ext 2808
Direct Dial: 01928 707808
Mobile: 07779676146

Exc

Filed on behalf of Norton Healthcare Limited
Deponent: S. Frankel
First Affidavit of the Deponent
Date of Swearing: 10 April 2006
Exhibits: SF1-2

IN THE MATTER of United States Patent Application Number 10/516,943

AFFIDAVIT OF SIMONE FRANKEL

I, SIMONE FRANKEL, of 29 West Grove, Woodford Green, Essex, IG8 7NR,
Personal Assistant to the European Director-Intellectual Property, MAKE OATH and
say as follows:

1. I am the Personal Assistant to the European Director-Intellectual Property, for
Norton Healthcare Limited (Norton) and I make this affidavit in support of Norton's
United States patent application number 10/516,943 entitled "Pharmaceutical
Composition". In so far as the content of this affidavit is within my personal
knowledge it is true, and so far as it is not within my personal knowledge it is true to
the best of my knowledge information and belief.
2. On 7 December 2004 I sent a letter by registered post to Mark Clifford Elliot at his
last known address of 40 Farleigh Road, Stoke Newington, London N16 7 TH
(appended as Exhibit SF 1).
3. On 7 December 2004 I sent a letter by registered post to Jacqueline Yvonne Allen
at her last known address of 13 Peartree Avenue, Earlsfield, London SW17 0JG
(appended as Exhibit SF2).
4. The letter to Mark Clifford Elliot was returned as undeliverable at the above
mentioned address.
5. The letter to Jacqueline Yvonne Allen was not returned as undeliverable but was
not replied to. I have never received any executed documents from Jacqueline Yvonne
Allen.

Sworn at Clifford Chance LLP,
6 Upper Bank Street
London
E14 5JJ
this 10th day of
April 2006

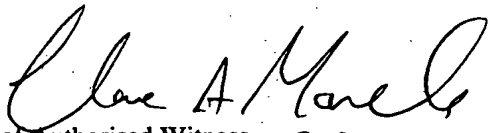


Signature of Deponent making the Affidavit

Before me,

.....*Clare Chance*.....
.....*Clifford Chance LLP*.....
.....*10 Upper Bank Street*.....
.....*London E14 5JJ*.....
.....*Solicitor*.....

CLIFFORD CHANCE
Limited Liability Partnership
10 Upper Bank Street
London E14 5JJ


Signature of Authorised Witness - *Solicitor*

Filed on behalf of Norton Healthcare Limited

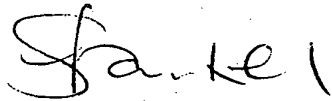
Deponent: S. Frankel

First Affidavit of the Deponent

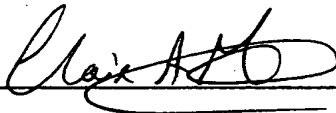
Date of Swearing: 10 April 2006

IN THE MATTER of United States Patent Application Number 10/516,943

EXHIBIT "SF1" TO THE AFFIDAVIT OF SIMONE FRANKEL

A handwritten signature in cursive script, appearing to read 'Frankel', written over a horizontal line.

SIMONE FRANKEL

A handwritten signature in cursive script, appearing to read 'Clair A. H.', written over a horizontal line.

PRACTISING SOLICITOR

Mark Clifford Elliott
40 Farleigh Road
Stroke Newington
London
N16 7TH

7th December 2004

Dear Mark,

Re: Documents for signature

Please find attached the following documents which require your signature.

- a) Declaration for Utility or Design
- b) Assignment
- c) Power of Attorney

I would appreciate if you could please sign and date in **BLUE INK** where indicated.

Please note that the Assignment Document requires two witness signatures and addresses.

If any of your information is incorrect, i.e. name, or address details, would you please amend and initial the amendment.

I hereby enclose a stamped addressed envelope for you to return the documents once executed.

Thank you in advance for your assistance.

Yours sincerely,

Simone Frankel
IP Legal Department

Encl.

Filed on behalf of Norton Healthcare Limited

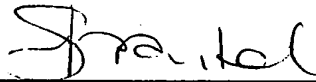
Deponent: S.Frankel

First Affidavit of the Deponent

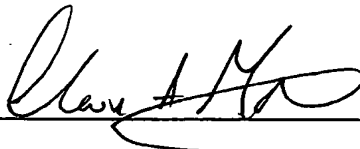
Date of Swearing: 10 April 2006

IN THE MATTER of United States Patent Application Number 10/516,943

EXHIBIT "SF2" TO THE AFFIDAVIT OF SIMONE FRANKEL



SIMONE FRANKEL



PRACTISING SOLICITOR

Jacqueline Yvonne Allen
13 Peartree Avenue
Earlsfield
London
SW17 0JG

7th December 2004

Dear Jacqueline,

Re: Documents for signature

Please find attached the following documents which require your signature.

- a) Declaration for Utility or Design
- b) Assignment
- c) Power of Attorney

I would appreciate if you could please sign and date in **BLUE INK** where indicated.

Please note that the Assignment Document requires two witness signatures and addresses.

If any of your information is incorrect, i.e. name, or address details, would you please amend and initial the amendment.

I hereby enclose a stamped addressed envelope for you to return the documents once executed.

Thank you in advance for your assistance.

Yours sincerely,

Simone Frankel
IP Legal Department

Encl.